

agency component requires the concurrence of the Deputy Commissioner for Operations or the Deputy Commissioner for Policy.

§ 3.10 Stay of review time.

Any filing with or review by the product jurisdiction officer stays the review clock or other established time periods for agency action for an application for marketing approval or required investigational notice during the pendency of the review by the product jurisdiction officer.

Subpart B [Reserved]

PART 5—DELEGATIONS OF AUTHORITY AND ORGANIZATION

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

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- 5.63 Detention of meat, poultry, eggs, and related products.
- 5.64 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.
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- 5.69 Notification of release for distribution of biological products.
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- 5.83 Approval of new animal drug applications and their supplements.
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- 5.85 Authority to ensure that mammography facilities meet quality standards.
- 5.86 Variances from performance standards for electronic products.
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- 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.
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- 5.98 Authority relating to medical device reporting procedures.
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Subpart C—Organization

- 5.200 Headquarters.
- 5.205 Chief Counsel, Food and Drug Administration.
- 5.210 FDA Public Information Offices.
- 5.215 Field structure.

AUTHORITY: 5 U.S.C. 504, 552, App. 2; 7 U.S.C. 138a, 2271; 15 U.S.C. 638, 1261–1282, 3701–3711a; secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 21 U.S.C. 41–50, 61–63, 141–149, 467f, 679(b), 801–886, 1031–1309; secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394); 35 U.S.C. 156; secs. 301, 302, 303, 307, 310, 311, 351, 352, 361, 362, 1701–1706, 2101 of the Public Health Service Act (42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 264, 265, 300u–300u–5, 300aa–1); 42 U.S.C. 1395y, 3246b, 4332, 4831(a), 10007–10008; E.O. 11490, 11921, and 12591.

SOURCE: 42 FR 15560, Mar. 22, 1977, unless otherwise noted.

Subpart A—Delegations of Authority to the Commissioner of Food and Drugs

§ 5.10 Delegations from the Secretary, the Assistant Secretary for Health, and Public Health Service Officials.

(a) The Assistant Secretary for Health has redelegated to the Commissioner of Food and Drugs, with authority to redelegate except when specifically prohibited, all authority delegated to the Assistant Secretary for Health by the Secretary of Health and Human Services, as follows:

(1) Functions vested in the Secretary under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*), the Filled Milk Act (21 U.S.C. 61–63), the Federal Import Milk Act (21 U.S.C. 141 *et seq.*), the Tea Importation Act (21 U.S.C. 41 *et seq.*), the Federal Caustic Poison Act (44 Stat. 1406), and The Fair Packaging and Labeling Act (15 U.S.C. 1451 *et seq.*), pursuant to section 12 of Reorganization Plan No. IV and Reorganization Plan No. 1 of 1953, including authority to administer oaths vested in

the Secretary of Agriculture by 7 U.S.C. 2217.

(2) Functions vested in the Secretary under section 301 (Research and Investigations); section 307 (International Cooperation); and section 311 (Federal-State Cooperation) of the Public Health Service Act (42 U.S.C. 241, 242I, 243), as amended, which relate to the functions of the Food and Drug Administration.

(3) Functions vested in the Secretary under sections 354 through 360F of the Public Health Service Act (42 U.S.C. 263b through 263n), as amended, which relate to electronic product radiation control.

(4) Functions vested in the Secretary under section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, which relate to the law enforcement functions of the Food and Drug Administration concerning the following products and activities: biologicals (including blood and blood products); interstate travel sanitation (except interstate transportation of etiologic agents under 42 CFR 72); food (including milk and food service sanitation and shellfish sanitation); and drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration.

(5) Functions vested in the Secretary under sections 351 and 352 of part F, subpart 1 of the Public Health Service Act (42 U.S.C. 262 and 263), as amended, Biological Products, insofar as they relate to the functions assigned to the Food and Drug Administration.

(6) Functions vested in the Secretary under section 302(a) of the Public Health Service Act (42 U.S.C. 242(a)), as amended, which relate to the determination and reporting requirements with respect to the medicinal and scientific requirements of the United States for controlled substances.

(7) Functions vested in the Secretary under section 303 of the Public Health Service Act (42 U.S.C. 242a), as amended, which relate to the authorization of persons engaged in research on the use and effect of drugs to protect the identity of their research subjects with respect to drugs scheduled under Pub. L. 91–513 for which an investigational new drug application is filed with the Food and Drug Administration and with re-

spect to all drugs not scheduled under Pub. L. 91–513.

(8) Functions vested in the Secretary pertaining to section 4 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (84 Stat. 1241) which relate to the determination of the safety and effectiveness of drugs or to approve new drugs to be used in the treatment of narcotic addicts.

(9) Functions vested in the Secretary pertaining to section 303(f) of the Controlled Substances Act (21 U.S.C. 823(f)) which relate to the determination of the qualifications and competency of practitioners wishing to conduct research with controlled substances listed in Schedule I of the Act, and the merits of the research protocol.

(10) Functions vested in the Secretary pertaining to provisions of the Controlled Substances Act (21 U.S.C. 801 *et seq.*) which relate to administration of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*).

(11) Functions vested in the Secretary under section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(12) Functions vested in the Secretary under section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(13) Functions vested in the Secretary under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

(14) Functions vested in the Secretary by amendments to the foregoing statutes subsequent to Reorganization Plan No. 1 of 1953.

(15) Function of issuing all regulations of the Food and Drug Administration, except as provided in § 5.11. The reservation of authority contained in Chapter 2–000 of the Department Organization Manual shall not apply.

(16) Functions vested in the Secretary under section 1103 of Executive Order 11490, as amended by Executive Order 11921, which relate to emergency health functions as they pertain to the

operations and functional responsibilities assigned to the agency. This authority shall be exercised in accordance with section 102 and pertinent sections of part 30 of Executive Order 11490 and guidelines promulgated by the Federal Preparedness Agency of the General Services Administration; Office of the Secretary, HHS; and Office of the Assistant Secretary for Health.

(17) Function vested in the Secretary of authorizing and approving miscellaneous and emergency expenses of enforcement activities.

(18) Functions vested in the Secretary under the Federal Advisory Committee Act, Public Law 92-463, to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and therefore may be closed to the public for those committees under the administrative jurisdiction of the Commissioner of Food and Drugs. This authority may be redelegated to a single official who reports directly to the Commissioner of Food and Drugs. This authority is to be exercised in accordance with the requirements of the Federal Advisory Committee Act and only with respect to the following:

(i) Meetings, to the extent that they directly involve review, discussion or consideration of records of the Department which are exempt from disclosure under 5 U.S.C. 552(b) (4), (6), and (7), namely, (a) records containing trade secrets and commercial or financial information obtained from a person and privileged or confidential; (b) personnel, medical and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; and (c) investigatory files compiled for law enforcement purposes;

(ii) Meetings to the extent that they involve the review, discussion, and evaluation of specific drugs and devices regulated by FDA which are intended to result in recommendations for regulatory decisions under the Federal Food, Drug, and Cosmetic Act and which are concerned with matters listed in 5 U.S.C. 552(b) (4), (5), and (7);

(iii) Meetings held for the sole purpose of considering and formulating advice which the committee will give or

any final report it will render, *Provided:*

(a) The meetings will involve solely the internal expression of views and judgments of the members and it is essential to close the meeting or portions thereof to protect the free exchange of such views and avoid undue interference with agency or committee operations, and such views if reduced to writing would be protected from mandatory disclosure under 5 U.S.C. 552(b);

(b) The meeting is closed for the shortest time necessary, summarizing the work of the committee during the closed session, and a report, prepared by the executive secretary will be made available promptly to the public.

(c) When feasible, the public is given a timely opportunity to present relevant information and views to the committee; and

(d) Concurrence for closing the meetings for such purpose is obtained from the Office of the General Counsel and the Office of Public Affairs.

(19) Functions vested in the Secretary under the second sentence of section 310(a) and under section 310(b) (Health Conferences and Health Education Information) of the Public Health Service Act (42 U.S.C. 242o), as amended, to call for a conference and invite as many health authorities and officials of State or local public or private agencies or organizations as deemed necessary or proper on subjects related to the functions of the Food and Drug Administration, and to issue information related to health for the use of the public and other pertinent health information for the use of persons and institutions concerned with health services when such information is related to the functions of the Food and Drug Administration.

(20) Functions vested in the Secretary under section 2101 of the Public Health Service Act (42 U.S.C. 219) as amended, to accept offers of gifts, excluding the acceptance of gifts of real property. Only the authority to accept unconditional gifts of personal property valued at \$5,000 or less may be redelegated.

(21) Functions vested in the Secretary under section 362 of the Public Health Service Act (42 U.S.C. 265), as

amended, which relate to the prohibition of the introduction of foods, drugs, devices, cosmetics, electronic products, and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health when such functions relate to the law enforcement functions of the Food and Drug Administration.

(22) Functions vested in the Secretary under section 1003(b)(3), title X, of the Public Works and Economic Development Act of 1965 (42 U.S.C. 3246b(b)(3)) to waive any matching requirements for programs or projects of State and local governments funded under title X of that act where it is determined that State or local governments concerned cannot reasonably obtain any non-Federal contributions.

(23) Functions vested in the Secretary under section 401(a) of the Lead-Based Paint Poisoning Prevention Act, as amended by Pub. L. 94-317 (42 U.S.C. 4831(a)) relating to the prohibition of the application of lead-based paint to cooking, drinking, or eating utensils.

(24) Functions vested in the Secretary for the health information and health promotion program under title XVII of the Public Health Service Act (42 U.S.C. 300u *et seq.*), as amended, insofar as the authorities pertain to functions assigned to the Food and Drug Administration. The delegation includes, but is not limited to, the authorities under: section 1702(a) (1) and (3) and section 1704 (1), (2), and (6). The delegation excludes the authority to select all Senior Executive Service, supergrade and equivalent, and Schedule C (GS-12 and above) positions; promulgate regulations; and submit reports to the President.

(25) To administer a Small Business Innovation Research Program under section 9 of the Small Business Act (15 U.S.C. 638), as amended. The delegation excludes the authority to promulgate regulations, establish advisory councils and committees, appoint members to advisory councils and committees, and submit reports to Congress.

(26) Functions vested in the Secretary under sections 982 and 983 of the Consumer-Patient Radiation Health and Safety Act of 1981 (42 U.S.C. 10007

and 10008), as amended. The delegation excludes the authority to promulgate regulations and submit reports to Congress. The authority delegated under section 983 of the Act may only be exercised as it relates to functions assigned to the Food and Drug Administration.

(27) Functions vested in the Secretary under section 156 of title 35 of the U.S. Code (35 U.S.C. 156), as amended, which allows for the extension of patent terms for human drug products, medical devices, food additives, and color additives subject to the Federal Food, Drug, and Cosmetic Act. These authorities may be redelegated except the authority to make due diligence determinations under section 156(d)(2)(B), which may not be redelegated to an Office below the Office of the Commissioner of Food and Drugs.

(28) Functions vested in the Secretary under section 1862(h) (1), (2)(A), and (3) of the Social Security Act (42 U.S.C. 1395y (h)(1), (2)(A), and (3)), as amended, which provides for a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under this title. The approval and issuance of regulations under that section are reserved to the Secretary, as provided in 21 CFR 5.11.

(29) Functions vested in the Secretary under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*) (the Act), as amended, and under Executive Order No. 12591 of April 10, 1987, as they pertain to the functions of the Food and Drug Administration. The delegation excludes the authority to promulgate regulations and submit reports to Congress; under section 11(a)(2) of the Act (15 U.S.C. 3710a(a)(2)) to approve agreements and contracts with invention management organizations; and under section 11(c)(3)(B) of the Act (15 U.S.C. 3710a(c)(3)(B)) to propose necessary statutory changes regarding conflict of interest.

(i) The authorities under sections 11(c)(5) (A) and (B) of the Act (15 U.S.C. 3710a(c)(5) (A) and (B)) to disapprove or require the modification of cooperative research and development agreements and licensing agreements after the agreement is presented to the Commissioner of Food and Drugs by the head

of the laboratory concerned, and to transmit written explanation of such disapproval or modification to the head of the laboratory concerned, may be re-delegated only to a senior official in the immediate office of the Commissioner.

(ii) The following authorities may not be redelegated: the authority under section 11(b)(3) of the Act (15 U.S.C. 3710a(b)(3)) to waive a right of ownership which the Federal Government may have to an invention made under a cooperative research and development agreement; the authority under section 11(b)(4) of the Act (15 U.S.C. 3710a(b)(4)) to permit employees or former employees to participate in efforts to commercialize inventions they made while in the service of the United States; the authority under section 11(c)(3)(A) of the Act (15 U.S.C. 3710a(c)(3)(A)) to review employee standards of conduct for resolving potential conflicts of interest; the authority under section 13(a)(1) of the Act (15 U.S.C. 3710c(a)(1)) to retain any royalties or other income, except as provided in section 13(a)(2) of the Act (15 U.S.C. 3710c(a)(2)); and the authority under section 13(a)(1)(A)(i) of the Act (15 U.S.C. 3710c(a)(1)(A)(i)) to pay royalties or other income the agency receives on account of an invention to the inventor if the inventor was an employee of the agency at the time the invention was made.

(iii) Any authorities under paragraph (a)(29) of this section delegated by the Commissioner of Food and Drugs may not be further redelegated.

(30) Functions vested in the Secretary under sections 4702, 4703, and 4704 of the Pesticide Monitoring Improvements Act of 1988 (21 U.S.C. 1401-1403) which relate to pesticide monitoring and enforcement information, foreign pesticide information, and pesticide analytical methods. The delegation excludes the authority to submit reports to Congress.

(31) Functions vested in the Secretary under the Government Patent Policy Act of 1980 as amended by the Federal Court Reorganization Act of 1984, as they pertain to the functions of the Food and Drug Administration (FDA). The delegated authorities, to be exercised in compliance with all exist-

ing rules and regulations regarding patent and invention rights and responsibilities, are restricted to the extent that 35 U.S.C. 203, as amended, may not be redelegated and that under 35 U.S.C. 207(a), the Assistant Secretary for Health is to be notified of any significant invention, patent, or license, so that the Assistant Secretary for Health may decide whether or not documentation concerning any such invention, patent, or license should be submitted to the Assistant Secretary for Health for signature. All other authorities may be redelegated to officials at the level equivalent to bureau and institute directors.

(i) Disposition of rights, 35 U.S.C. 202(c)(7), as amended: The authority to permit a nonprofit organization to assign the rights to a subject invention in the United States to organizations which do not have as one of their primary functions the management of inventions.

(ii) Disposition of rights, 35 U.S.C. 202(d), as amended: The authority to permit a contractor to grant requests for retention of rights by the inventor.

(iii) Disposition of rights, 35 U.S.C. 202(e), as amended: The authority to transfer or assign whatever rights FDA may acquire in the subject invention in any case when an agency employee is a coinventor of any invention made under a funding agreement with a nonprofit organization or small business firm. Such rights may be transferred or assigned from the FDA employee to the contractor subject to the conditions set forth in this chapter.

(iv) March-in-rights, 35 U.S.C. 203, as amended: The authority to require the contractor to grant nonexclusive, partially exclusive, or exclusive licenses to responsible applicant(s), or the authority for FDA to grant such licenses, provided such action would be in the best interest of FDA, in accordance with all provisions of this section.

(v) Preference for United States industry, 35 U.S.C. 204, as amended: The authority to waive the preference for U.S. industry requirement.

(vi) Domestic and foreign protection of federally owned inventions, 35 U.S.C. 207(a) as amended, the authority to:

(A) Apply for, obtain, and maintain patents or other forms of protection in

the United States and in foreign countries on inventions in which the Federal Government owns a right, title, or interest;

(B) Grant nonexclusive, exclusive, or partially exclusive licenses under federally owned patent applications, patents, or other forms of protection obtained, royalty-free or for royalties or other consideration, and on such terms and conditions, including the grant to the licensee of the right of enforcement pursuant to the provisions of chapter 29 of title 35 as determined appropriate in the public interest;

(C) Undertake all other suitable and necessary steps to protect and administer rights to federally owned inventions on behalf of the Federal Government either directly or through contract; and

(D) Transfer custody and administration, in whole or in part, to another Federal agency, of the right, title, or interest in any federally owned invention.

(vii) Determination as to domestic rights and notice to employee of determination, 45 CFR 7.3 and 7.7, as amended, authority to:

(A) Leave title to invention in the FDA employee inventor where the Government has insufficient interest in an invention to obtain the entire domestic right, title, and interest therein; and

(B) Notify the FDA employee inventor of the determination in writing.

(32) Functions vested in the Secretary under sections 2312(a)(1) and (2)(B), (b), and (c) (Use of Investigational New Drugs with Respect to Acquired Immunodeficiency Syndrome); 2314(c) (Scientific and Ethical Guidelines for Certain Treatments); and 2317 (d) and (e) (Information Services) of title XXIII of the Public Health Service Act (42 U.S.C. 300cc-12(a)(1) and (2)(B), (b) and (c), 300cc-14(c) and 300cc-17 (d) and (e), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegation excludes the authority to promulgate regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(33) Functions vested in the Secretary under section 2672(a)(1) (A) and (B) (Provisions Relating to Blood Banks) and section 2672(a)(2) (Information and Training Programs) of the Public Health Service Act (42 U.S.C. 300ff et seq.), as amended, insofar as these authorities pertain to the functions assigned to the Food and Drug Administration. The delegations exclude the authority to promulgate regulations, submit reports to the Congress, establish advisory committees or national commissions, and appoint members to such committees or commissions.

(34) Functions vested in the Secretary under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter, which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of this section. The delegation excludes the authority to submit reports to Congress.

(35) Functions vested in the Secretary under part C, subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa-25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 note), as amended hereafter, as follows:

(i) Section 2125 of the Public Health Service Act (42 U.S.C. 300aa-25)—Recording and reporting of information.

(ii) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa-27)—Mandate for safer childhood vaccines.

(iii) Section 2128 of the Public Health Service Act (42 U.S.C. 300aa-28)—Manufacturer recordkeeping and reporting.

(iv) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies.

(v) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks.

(vi) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

(vii) The delegation excludes the authority to issue regulations and submit reports to Congress.

(36) Functions vested in the Secretary under section 354(b) through (l) and (n), (o), (q), and (r) of the Public Health Service Act (section 2 of the Mammography Quality Standards Act of 1992 (Pub. L. 102-539)), as amended, which deal with the certification of mammography facilities. The delegation excludes the authority to submit reports to Congress.

(37) Functions vested in the Secretary under section 811(h)(4) of the Controlled Substances Act (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended) to provide responses to the Drug Enforcement Administration's temporary scheduling notices. The delegation excludes the authority to submit reports to Congress.

(b) The Chief Counsel of the Food and Drug Administration, i.e., the Associate General Counsel in charge of the Food and Drug Division, has been authorized to report apparent violations to the Department of Justice for the institution of criminal proceedings, pursuant to section 305 of the Federal Food, Drug, and Cosmetic Act, section 4 of the Federal Import Milk Act, and section 9(b) of the Federal Caustic Poison Act.

(c) The Director, Office of Management, Public Health Service, has re-delegated to the Commissioner of Food and Drugs, with authority to redelegate, the authority to certify true copies of any books, records, or other documents on file within the Food and Drug Administration or extracts from such; to certify that true copies are true copies of the entire file of the Administration; to certify the complete original record or to certify the non-existence of records on file within the Administration; and to cause the Seal of the Department to be affixed to such certifications and to agreements, awards, citations, diplomas, and similar documents.

(d) The Executive Officer, Public Health Service, has re-delegated to the Commissioner of Food and Drugs appeal authority to take final action upon an individual's appeal of a refusal to correct or amend the individual's

record when the appeal has been made by the individual under Privacy Act regulations (part 21 of this chapter and 45 CFR part 5b). The authority may not be re-delegated.

(e) [Reserved]

(f) The Secretary of Health and Human Services has re-delegated to the Commissioner of Food and Drugs, or his designee, the authority to take final action on matters pertaining to section 203 of the Equal Access to Justice Act (5 U.S.C. 504), and to develop procedures and regulations where necessary to supplement the Department's regulations, 45 CFR part 13.

[42 FR 15560, Mar. 22, 1977]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 5.10, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§ 5.11 Reservation of authority.

(a) Notwithstanding provisions of § 5.10 or any previous delegations of authority to the contrary, the Secretary reserves the authority to approve regulations of the Food and Drug Administration, except regulations to which sections 556 and 557 of title 5 U.S.C. apply, which:

(1) Establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, or other subjects of regulation; or

(2) Present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics, medical devices, or other subjects of regulation.

(b) Nothing in this section precludes the Secretary from approving a regulation, or being notified in advance of an action, to which sections 556 and 557 of title 5 U.S.C. apply, which meets one of the criteria in paragraph (a) of this section.

(c) This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the Food and Drug Administration, any agency, officer, or employee of the United States, or any person. Regulations issued by the Food

and Drug Administration without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

[47 FR 16318, Apr. 16, 1982]

Subpart B—Redelegations of Authority from the Commissioner of Food and Drugs

§ 5.20 General redelegations of authority from the Commissioner to other officers of the Food and Drug Administration.

(a) Final authority of the Commissioner of Food and Drugs is redelegated as set forth in this subpart.

(b) The Deputy Commissioner and the Associate Commissioner for Regulatory Affairs are authorized to perform all of the functions of the Commissioner of Food and Drugs.

(c) During the absence or disability of the Commissioner or in the event of a vacancy in that position, the first official who is available in the following positions, or who has been designated by the Commissioner to act in such position, shall act as Commissioner:

- (1) Deputy Commissioner.
- (2) Associate Commissioner for Regulatory Affairs.
- (3) Associate Commissioner for Management and Operations.

For a planned period of absence, the Commissioner may specify a different order of succession.

(d) Authority delegated to a position by title may be exercised by a person officially designated to serve in that position in an acting capacity or on a temporary basis, unless prohibited by a restriction in the document designating him as “acting” or unless not legally permissible.

(e) The Deputy Commissioner for Operations is authorized to make determinations that advisory committee meetings are concerned with matters listed in 5 U.S.C. 552(b) and may be closed to the public in accordance with § 5.10(a)(18).

(f)(1) The Deputy Commissioner for Policy and the Associate Commissioner for Policy Coordination are authorized to perform any of the functions of the Commissioner of Food and Drugs with

respect to the issuance of FEDERAL REGISTER notices and proposed and final regulations of the Food and Drug Administration.

(2) The Deputy Commissioner for Policy is authorized to issue responses to the following matters under part 10 of this chapter as follows:

- (i) Requests for waiver, suspension, or modification of procedural requirements under § 10.19;
- (ii) Citizen petitions under § 10.30;
- (iii) Petitions for reconsideration under § 10.33;
- (iv) Petitions for stay under § 10.35; or
- (v) Requests for advisory opinions under § 10.85.

(3) With respect to any matter delegated to the Deputy Commissioner for Policy under this paragraph, the Deputy Commissioner for Policy is authorized to perform the functions of the Commissioner under §§ 10.40, 10.45, 10.50, 10.55, 10.60, 10.65, 10.80, 10.90, and 10.95 and of the Deputy Commissioner under § 10.206 (g) and (h) of this chapter.

(g) The following officials are authorized to perform all the functions of the officials under them in their respective offices:

- (1) Deputy Commissioner for Operations.
- (2) Deputy Commissioner for Policy.
- (3) Deputy Commissioner for External Affairs.
- (4) Deputy Commissioner for Management and Systems.

(h) The Chief Mediator and Ombudsman is designated as User Fee Waiver Officer and is authorized to perform all of the functions of the Commissioner under the Prescription Drug User Fee Act of 1992 (21 U.S.C. 379h(d)), as amended hereafter, relating to the authority to waive or reduce user fees. The User Fee Waiver Officer's authority may be redelegated to the Deputy Chief Mediator and Ombudsman and to the Deputy User Fee Waiver Officer without further redelegation. The Deputy Commissioner for Operations is designated User Fee Appeals Officer and is authorized to hear and decide user fee waiver appeals. The decision of the User Fee Appeals Officer will constitute final agency action on such matters.

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(i) Authority delegated in the following sections of this subpart may not be redelegated.

[43 FR 20487, May 12, 1978, as amended at 48 FR 43300, Sept. 23, 1983; 56 FR 36001, July 30, 1991; 57 FR 12875, Apr. 14, 1992; 58 FR 17095, Apr. 1, 1993; 59 FR 14549, Mar. 29, 1994; 61 FR 2414, Jan. 26, 1996; 62 FR 923, Jan. 7, 1997]

§ 5.21 Emergency functions.

Each Regional Food and Drug Director is authorized, during any period when normal channels of direction are disrupted between the Food and Drug Administration headquarters and his region, to fully represent the Food and Drug Administration within his region in consonance with the Department of Health and Human Services regional emergency plans and to exercise the authority of the Commissioner for supervision of and direction to all Food and Drug Administration activities and use of resources within his region for continuity and for Federal Emergency Health Service operations. These same officials are authorized to provide in Regional Emergency Plans for the delegation of Food and Drug Administration regional authorities to heads of field activities when such activities are cut off from national and regional headquarters.

§ 5.22 Certification of true copies and use of Department seal.

(a) The following officials are authorized to certify true copies of or extracts from any books, records, papers, or other documents on file within the Food and Drug Administration, to certify that copies are true copies of the entire file, to certify the complete original record, or to certify the non-existence of records on file within the Food and Drug Administration, and to cause the seal of the Department to be affixed to such certifications:

- (1) The Deputy Commissioners.
- (2) The Associate and Deputy Associate Commissioners.
- (3)(i) The Director, Office of Executive Operations.
- (ii) The Director, Executive Secretariat.
- (iii) The Director, Program Management Staff.

(4) The Executive Assistant to the Commissioner, Office of the Commissioner.

(5)(i) The Director and Deputy Director, Office of Enforcement, Office of Regulatory Affairs (ORA).

(ii) The Director and Deputy Director, Office of Regional Operations, ORA.

(iii) The Director and Deputy Director, Office of Resource Management, ORA.

(iv) The Director, Division of Management Operations, and Chief, Administrative Management Branch, Office of Resource Management, ORA.

(v) The Director, FDA History Staff, ORA.

(6)(i) The Director, Division of Management Systems and Policy, Office of Management (OM).

(ii) The Chief, Dockets Management Branch, Division of Management Systems and Policy, OM.

(7) The Director, Freedom of Information Staff, Office of Public Affairs.

(8)(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Director, Office of Management, CBER.

(iii) The Directors and Deputy Directors of the Office of Compliance, CBER.

(iv) The Director of Congressional and Public Affairs Staff, Office of the Center Director, CBER.

(v) The Chief, Surveillance and Policy Branch and Consumer Safety Officers, Office of Compliance, CBER.

(9)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Management Systems, CFSAN.

(iv) The Director, Office of Cosmetics and Colors, CFSAN.

(v) The Director, Office of Plant and Dairy Foods Beverages, CFSAN.

(vi) The Director, Office of Seafood, CFSAN.

(vii) The Director, Office of Special Nutritional, CFSAN.

(viii) The Director, Office of Special Research Skills, CFSAN.

(ix) The Director, Office of Constituent Operations, CFSAN.

(x) The Director, Office of Field Programs, CFSAN.

(xi) The Director, Office of Pre-market Approval, CFSAN.

(xii) The Director, Office of Scientific Analysis and Support, CFSAN.

(xiii) The Director, Office of Food Labeling, CFSAN.

(10)(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director, Office of Management Services, CDRH.

(iii) The Director and Deputy Director, Office of Compliance, CDRH.

(iv) The Director and Deputy Director, Division of Compliance Programs, CDRH.

(v) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

(11)(i) The Director and Deputy Directors, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Management, CVM.

(iii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iv) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(v) The Chief, Case Guidance Branch, Division of Compliance, Office of Surveillance and Compliance, CVM.

(12)(i) The Director and Deputy Director, National Center for Toxicological Research (NCTR).

(ii) The Director, Office of Research Support, NCTR.

(13)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Management, CDER.

(iii) The Director and Deputy Director, Office of Compliance, CDER.

(iv) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, and the Director and Deputy Director of the Office of Epidemiology and Biostatistics, Office of Review Management, CDER.

(v) The Directors and Deputy Directors of the Offices of Testing and Research, Generic Drugs, New Drug Chemistry, and Clinical Pharmacology

and Biopharmaceutics, Office of Pharmaceutical Science, CDER.

(vi) The Chief, Freedom of Information Staff, Office of Training and Communications, CDER.

(vii) The Directors of the Divisions of Labeling and Nonprescription Drug Compliance, Prescription Drug Compliance and Surveillance, and Manufacturing and Product Quality, Office of Compliance, CDER.

(viii) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(14)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) The Director, St. Louis Branch.

(iv) The Director, New York Laboratory Division, Northeast Region.

(v) The Director, Southeast Regional Laboratory, Southeast Region.

(vi) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to cause the seal of the Department to be affixed to agreements, awards, citations, diplomas, and similar documents:

(1) Deputy Commissioners.

(2) The Associate and Deputy Associate Commissioners.

(3) The Director, Office of Human Resources Management, Office of Management.

(c) The Chief, Regulations Editorial Section and his/her alternates, Regulations Policy and Management Staff, Office of Policy, Office of the Commissioner are authorized to certify true copies of FEDERAL REGISTER documents.

[50 FR 4858, Feb. 4, 1985, as amended at 58 FR 17095, Apr. 1, 1993; 60 FR 26826, May 19, 1995; 61 FR 9639, Mar. 11, 1996; 62 FR 2554, Jan. 17, 1997]

§ 5.23 Disclosure of official records.

(a) The following officials are authorized to make determinations to disclose official records and information under part 20 of this chapter, except that only the officials listed in paragraph (a)(1) of this section may disclose official records and information under §§ 20.82 and 20.85 of this chapter, and only officials listed in paragraph (a)(10)

of this section may disclose information under § 20.89(c) of this chapter.

(1) Associate and Deputy Associate Commissioners.

(2)(i) The Director, Office of the Executive Assistant.

(ii) The Director, Executive Secretariat.

(iii) The Director, Program Management Staff.

(3) Executive Officer, Office of the Commissioner.

(4) The Chief, Dockets Management Branch, Division of Management Systems and Policy, Office of Management and Operations.

(5) Program officials at all organizational levels down to and including branch level for all Headquarters organizations.

(6) Regional Food and Drug Directors and District Directors.

(7) Director, Winchester Engineering and Analytical Center.

(8) Chiefs of branches Field/District Offices and Centers.

(9) Freedom of Information Officers and other employees engaged in Freedom of Information activities.

(10)(i) The Associate Commissioner for Regulatory Affairs, Deputy Associate Commissioner for Regulatory Affairs, and Director, Office of Enforcement, FDA.

(ii) The Director, Deputy Director, and Associate Director for Policy Coordination and Public Affairs, Center for Biologics Evaluation and Research (CBER), and Director, Division of Congressional and Public Affairs, CBER.

(iii) The Director, Deputy Directors, and Associate Director for Science and Medical Affairs, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(v) The Director, Center for Food Safety and Applied Nutrition (CFSAN), and Deputy Director for Systems and Support, CFSAN.

(vi) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(vii) The Director, Deputy Director, and Associate Director for Scientific Coordination, National Center for Toxicological Research (NCTR).

(b) The Chief, Product Information Management Branch, Division of Database Management, Office of Management, Center for Drug Evaluation and Research (CDER), is authorized to sign affidavits regarding the presence or absence of records of Registration of Drug Establishments.

(c) The following officials are authorized to sign affidavits regarding the presence or absence of medical device establishment registration records:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) The Director, Division of Product Surveillance, Office of Compliance and Surveillance, CDRH.

(4) The Chief, Device Registration and Listing Branch, Division of Product Surveillance, Office of Compliance and Surveillance, CDRH.

(d) The Chief of the Records Section of the Administrative Services Branch, Division of Management Services, Office of Management and Operations, is authorized to sign affidavits regarding the presence or absence of records in the files of that section.

(e) The Director and Deputy Director, Division of Product Certification, Office of Biological Product Review, Center for Biologics Evaluation and Research, are authorized to sign affidavits regarding the presence or absence of records of registration of blood product establishments.

[43 FR 29286, July 7, 1978, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 51 FR 11428, Apr. 3, 1986; 54 FR 8315, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 37419, July 22, 1994; 62 FR 2554, Jan. 17, 1997]

§ 5.24 Authority relating to technology transfer.

(a) The Associate Commissioner for Regulatory Affairs is authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner regarding the authority to disapprove or require modification of cooperative research and development agreements and licensing

agreements and transmit written explanation of such approval or disapproval to the head of the laboratory concerned under sections 11(c)(5) (A) and (B) of the Stevenson-Wydler Technology Innovation Act of 1980 (the Act) (15 U.S.C. 3710a(c)(5) (A) and (B)), as amended.

(b) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs as requested by the Commissioner under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*), as amended, and Executive Order 12591 of April 10, 1987, except to the extent that redelegation of those functions is specifically limited in § 5.10(a)(29) of this part, as they pertain to the functions of their respective organizations, including the authority to perform the functions of laboratory directors under the Act as the heads of their respective Federal laboratories, subject to the discretion of the Commissioner of Food and Drugs to require that agreements entered into under section 11(a) of the Act (15 U.S.C. 3710a(a)) include provisions in accordance with section 11(c)(5)(A) of the Act (15 U.S.C. 3710a(c)(5)(A)):

(1) The Director, Center for Biologics Evaluation and Research.

(2) The Director, Center for Devices and Radiological Health.

(3) The Director, Center for Drug Evaluation and Research.

(4) The Director, Center for Food Safety and Applied Nutrition.

(5) The Director, Center for Veterinary Medicine.

(6) The Director, National Center for Toxicological Research.

(7) The Associate Commissioner for Regulatory Affairs.

[53 FR 26049, July 11, 1988]

§ 5.25 Research, investigation, and testing programs and health information and health promotion programs.

(a) The following officials are authorized under sections 301, 307, 311, 1701, 1702, 1703, and 1704 of the Public Health Service Act (the act) to establish research, investigation, and testing programs and health information and health promotion programs, which re-

late to their assigned functions, and to approve grants for conducting such programs:

(1) The Director and Deputy Director, National Center for Toxicological Research.

(2) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research.

(4) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition.

(5) The Director and Deputy Director, Center for Veterinary Medicine.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(7) The Director, Office of Orphan Products Development.

(b) The Director and Deputy Director, CDRH, are authorized to establish an electronic product radiation control program and to approve grants for conducting the program under section 356 of the act.

(c) The Associate and Deputy Associate Commissioner for Management and Operations, the Director and Deputy Director of the Division of Contracts and Grants Management of the Office of Management and Operations, the Chief of the State Contracts and Assistance Agreements Branch, and the Chief of the Grants and Assistance Agreements Section of that Division and Office are authorized to sign and issue all notices of grant awards and amendments thereto and sign and issue notices of suspension and termination thereof for grants approved under the authority delegated in paragraphs (a) and (b) of this section.

(d) The Director of the National Center for Toxicological Research is authorized under section 301, as amended by Pub. L. 95–622, of the Public Health Service Act to make available to educational institutions, for biomedical and behavioral research, laboratory animals bred for research purposes of

the Center which are not required to support Center research programs.

[45 FR 7783, Feb. 5, 1980, as amended at 45 FR 27924, Apr. 25, 1980; 46 FR 17758, Mar. 20, 1981; 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 57 FR 45295, Oct. 1, 1992; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997]

§ 5.26 Service fellowships.

Under authority of sections 207(g) and 208(f) of the Public Health Service Act (42 U.S.C. 209(g) and 210(f)), and within the limits of an approved service fellowship plan, the following officials are authorized to designate persons to receive service fellowships, appoint service fellows, and determine specific stipend rates for individual actions within the ranges established under an approved service fellowship plan:

- (a) Deputy Commissioners.
- (b) The Director and Deputy Director, National Center for Toxicological Research (NCTR), and the Director, Office of Management, NCTR.
- (c) The Director, Center for Devices and Radiological Health (CDRH), the Deputy Director for Science, CDRH, the Deputy Director for Regulations and Policy, CDRH, and the Director, Office of Management Services, CDRH.
- (d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), the Associate Director for Research, CBER, and Office Directors.
- (e) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and Director, Office of Management Systems, CFSAN.
- (f) The Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director, Office of Management, CVM.
- (g) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Management, CDER.
- (h) The Director, Office of Resource Management, Office of Regulatory Affairs.

- (i) The Director, Office of Human Resources Management, Office of Management and Systems.

[48 FR 56946, Dec. 27, 1983, as amended at 49 FR 14932, 14936, Apr. 16, 1984; 50 FR 4859, Feb. 4, 1985; 54 FR 8316, Feb. 28, 1989; 59 FR 5317, Feb. 4, 1994; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997]

§ 5.27 Patent term extensions for human drug products, medical devices, and food and color additives.

The Associate Commissioner for Health Affairs is authorized to perform the functions delegated to the Commissioner under section 156 of title 35 U.S. Code (35 U.S.C. 156), except for the holding of informal hearings pursuant to 35 U.S.C. 156(d)(2)(B)(ii).

[50 FR 9424, Mar. 8, 1985]

§ 5.28 Cardiac pacemaker devices and pacemaker leads.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to a registry of all cardiac pacemaker devices and pacemaker leads for which payment was made under the Social Security Act (42 U.S.C. 1395y(h)(1), (2)(A), and (3)), as amended.

[51 FR 25883, July 17, 1986]

§ 5.29 Functions pertaining to safer vaccines.

The Director, Center for Biologics Evaluation and Research (CBER), and the Associate Director for Policy Coordination and Public Affairs, CBER, are authorized to perform the functions of the Commissioner of Food and Drugs under part C, subtitle 2 of title XXI of the Public Health Service Act (42 U.S.C. 300aa-25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa-1 note), as amended hereafter, as follows:

- (a) Section 2125 of the Public Health Service Act (42 U.S.C. 300aa-25)—Recording and reporting of information.
- (b) Section 2127 of the Public Health Service Act (42 U.S.C. 300aa-27)—Mandate for safer childhood vaccines.
- (c) Section 2128 of the Public Health Service Act (42 U.S.C. 300aa-28)—Manufacturer recordkeeping and reporting.

(d) Section 312 of the National Childhood Vaccine Injury Act of 1986—Related studies, except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and 312(d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(e) Section 313 of the National Childhood Vaccine Injury Act of 1986—Study of other vaccine risks, except that the authority to provide for notice and opportunity for public hearing on the establishment of guidelines regarding the risks to children of certain vaccines under section 313(a)(1)(B) and (b) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(f) Section 314 of the National Childhood Vaccine Injury Act of 1986—Review of warnings, use instructions, and precautionary information.

[58 FR 17106, Apr. 1, 1993]

§ 5.30 Hearings.

(a) The following officials are authorized to designate officials to hold informal hearings that relate to their assigned functions under sections 305, 404(b), and 801(a) of the Federal Food, Drug, and Cosmetic Act; section 6 of the Fair Packaging and Labeling Act; section 9(b) of the Federal Caustic Poison Act; and section 5 of the Federal Import Milk Act. Officials so designated are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer to take from any person an oath, affirmation, affidavit, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Di-

rector and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(4) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(5) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(6) Regional Food and Drug Directors.

(7) District Directors.

(8) The Director, St. Louis Branch.

(b) The Director and Deputy Director, CDRH, are authorized to hold hearings, and to designate other officials to hold informal hearings, under section 360(a) of the Public Health Service Act.

(c) The following officials are authorized to serve as the presiding officer, and to designate other Food and Drug Administration employees to serve as the presiding officer, at a regulatory hearing and to conduct such a hearing pursuant to the provisions of part 16 of this chapter. An official can serve as the presiding officer in a particular hearing only if he or she satisfies the requirements of § 16.42(b) of this chapter with respect to the action that is the subject of the hearing. Such officials are delegated authority vested in the Secretary of Agriculture by 7 U.S.C. 2217 (43 Stat. 803) to administer or to take from any person an oath, affirmation, or deposition for use in any prosecution or proceeding under, or in enforcement of, any law as cited in this part:

(1) The Associate Commissioner for Health Affairs.

(2) The Director and Deputy Directors, CFSAN.

(3) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER; the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(4) The Director and Deputy Director, CDRH.

(5) The Director and Deputy Director, CVM.

(6) The Director and Deputy Director, CBER, and the Directors and Deputy Directors of the Offices of Biological Product Review, Biologics Research, and Compliance, CBER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(9) The Director, St. Louis Branch.

(10) Such other FDA official as is designated by the Commissioner by memorandum in the proceeding.

[48 FR 8440, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14932, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8316, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 59 FR 42491, Aug. 18, 1994; 62 FR 2554, Jan. 17, 1997]

§ 5.31 Petitions under part 10.

(a) For drugs assigned to their organizations, the following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors of the Offices of Biological Product Review and Biologics Research, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Biological Product Review and Biologics Research, CBER.

(2)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iv) The Director and supervisory consumer safety officers, Pilot Drug Evaluation Staff, Office of the Center Director, CDER.

(b) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter

requesting in vitro test modifications under § 331.29 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(c) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter for a stay of an effective date or for an exemption from the tamper-resistant packaging and labeling requirements set forth in § 211.132, § 700.25, or § 800.12 of this chapter for certain over-the-counter human drug and cosmetic products and medical devices which relate to the assigned functions of the respective organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director and Deputy Director, Center for Devices and Radiological Health.

(d) The following officials are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter requesting exemption from the general pregnancy-nursing warning for over-the-counter (OTC) drugs required under § 201.63 of this chapter, requesting exemption from a general overdose warning required under § 330.1(g) of this chapter, and requesting exemption from OTC drug administrative procedures under § 330.10 of this chapter:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(2) The Director, Office of Drug Evaluation V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Division of Over-the-Counter Drug

Products, Office of Drug Evaluation V, Office of Review Management, CDER.

(e)(1) The following officials are authorized to issue 180-day tentative responses to citizen petitions on food and cosmetic matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Cosmetics and Colors, CFSAN.

(iv) The Director, Office of Food Labeling, CFSAN.

(v) The Director, Office of Premarket Approval, CFSAN.

(vi) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(vii) The Director, Office of Seafood, CFSAN.

(viii) The Director, Office of Special Nutritionals, CFSAN.

(2) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to issue 180-day tentative responses to citizen petitions on animal food and drug matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(3) The Director and Deputy Director, CBER, are authorized to issue 180-day tentative responses to citizen petitions on biological product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(4) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to issue 180-day tentative responses to citizen petitions on drug product matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(5) The Director and Deputy Director, CDRH, are authorized to issue 180-day tentative responses to citizen petitions on medical device matters under § 10.30(e)(2)(iii) of this chapter that relate to the assigned functions of that Center.

(f)(1) The Director and Deputy Director, CBER, are authorized to grant or

deny citizen petitions submitted under § 10.30 of this chapter on drug and biological product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.68 *Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products*;

(ii) Section 5.69 *Notification of release for distribution of biological products*;

(iii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iv) Section 5.80 *Approval of new drug applications and their supplements*; and

(v) Section 5.82 *Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements*.

(vi) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment*.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER, are authorized to grant or deny citizen petitions submitted under § 10.30 of this chapter on drug product matters in program areas where they have been delegated final approval authority in the following sections of this part:

(i) Section 5.70 *Issuance of notices implementing the provisions of the Drug Amendments of 1962 (DESI)*;

(ii) Section 5.71 *Termination of exemptions for new drugs for investigational use in human beings or in animals*;

(iii) Section 5.73 *Certification of insulin*;

(iv) Section 5.74 *Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin*;

(v) Section 5.75 *Designation of official master and working standards for anti-biotic drugs*;

(vi) Section 5.76 *Certification of anti-biotic drugs*;

(vii) Section 5.78 *Issuance, amendment, or repeal of regulations pertaining to anti-biotic drugs*;

(viii) Section 5.80 *Approval of new drug applications and their supplements*; and

(ix) Section 5.82 *Issuance of notices relating to proposals to refuse approval or*

to withdraw approval of new drug applications and their supplements.

(x) Section 5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(3) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, except for those drug products listed in §314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(4) The Director and Deputy Director, Office of Biological Product Review, CBER, for those drug products listed in §314.440(b) of this chapter, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter seeking a determination of the suitability of an abbreviated new drug application for a drug product.

(5) For drugs assigned to their organization, the following officials are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter from sponsors of an investigational new drug application who request approval to ship in interstate commerce, in accordance with §2.125(j) of this chapter, an investigational new drug for human use containing a chlorofluorocarbon.

(i) The Director and Deputy Director, CBER.

(ii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(6) The Director and Deputy Director, CVM, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter from sponsors of an investigational new animal drug application who request approval to ship in interstate commerce, in accordance with §21.125(j) of this chapter, an investigational new animal drug for animal use containing a chlorofluorocarbon.

(7) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM, are authorized to issue responses to citizen petitions submitted under §10.30 of this chapter, seeking a determination of the suitability of an abbreviated

new animal drug application for an animal drug product.

(8) The Director and Deputy Director, CVM, are authorized to grant or deny citizen petitions submitted under §10.30 of this chapter concerning actions they are authorized to take under §5.99 *Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.*

(g) The Director and Deputy Directors, CDRH, and the Director, Office of Compliance, CDRH, are authorized to grant or deny citizen petitions submitted under §§10.30 and 821.2(b) of this chapter, requesting an exemption or variance from medical device tracking requirements in part 821 of this chapter.

[47 FR 38480, Aug. 31, 1982]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §5.31, see the List of CFR Sections Affected in the Finding Aids section of this volume.

§5.32 Authority relating to determination of product primary jurisdiction.

The FDA ombudsman as product jurisdiction officer is authorized to determine whether the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), or the Center for Drug Evaluation and Research (CDER) has primary responsibility for premarket review and regulation of a product that constitutes a combination of a drug, device, or biological product under section 503(g)(1) of the Federal Food, Drug, and Cosmetic Act or that is a drug, device or biologic product where the center with primary jurisdiction is unclear or in dispute.

[56 FR 58758, Nov. 21, 1991]

§5.33 Premarket approval of a product that is or contains a biologic, a device, or a drug.

For a product that is or contains a biologic, a device, or a drug, the following officials in the Center for Biologics Evaluation and Research, Center for Devices and Radiological Health, or Center for Drug Evaluation and Research who currently hold delegated premarket approval authority for biologics, devices, or drugs, respectively, are hereby delegated all the authorities

necessary for premarket approval of any product that is a biologic, a device, or a drug, or any combination of two or more of these products:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Biological Product Review, CBER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH) and the Director, Office of Device Evaluation, CDRH.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

[56 FR 58759, Nov. 21, 1991, as amended at 62 FR 2555, Jan. 17, 1997]

§ 5.34 Authority to select temporary voting members for advisory committees and authority to sign conflict of interest waivers.

(a) Each center director is authorized to select members of, and consultants to, scientific and technical FDA advisory committees under that center's management to serve temporarily as voting members on another advisory committee under that center's management when expertise is required that is not available among current voting standing members of a committee or to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. When additional voting members are added to a committee to provide needed expertise not available among current voting standing members of a committee, a quorum will be based on the total of regular and added members. Authority to select temporary voting members to advisory committees if such voting members are serving on an advisory committee managed by another center has not been redelegated. This authority will continue to be exercised by the Commissioner or his designee.

(b) Each center director is authorized, under 18 U.S.C. 208(b)(1), to sign conflict of interest waivers for special government employees without substantial interest to serve as consult-

ants to advisory committees or in any other capacity within the centers except as advisory committee members.

[58 FR 39142, July 22, 1993]

§ 5.35 Enforcement activities.

(a) Designated officers and employees of the Food and Drug Administration who have been issued the Food and Drug Administration official credentials consisting of Form FDA-200A, Identification Record, and Form FDA-200B, Specification of General Authority, are authorized:

(1) To conduct examinations, inspections, and investigations; to collect and obtain samples; to have access to and to copy and verify records as authorized by law; to make seizures of items under section 702(e)(5) of the Federal Food, Drug, and Cosmetic Act (the act); and to supervise compliance operations for the enforcement of the act, the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Import Milk Act, the Filled Milk Act, the Tea Importation Act, and sections 351 and 354 through 361 of the Public Health Service Act.

(2) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(b) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to conduct examinations, investigations, or inspections under the act relating to counterfeit drugs and issued the Food and Drug Administration Official Credential consisting of Form FDA-200D, Special Authority for Criminal Investigators, is authorized to do the following:

(1) As set forth under section 702(e)(1) through (e)(5) of the act:

(i) Carry firearms;

(ii) Serve and execute search warrants and arrest warrants;

(iii) Execute seizure by process issued pursuant to libel under section 304 of the act;

(iv) Make arrests without warrant for an offense under the act with respect to counterfeit drugs if the offense is committed in the presence of the

criminal investigator or, in the case of a felony, if the investigator has probable cause to believe that the person so arrested has committed, or is committing, such offense; and

(v) Make, prior to the institution of libel proceedings under section 304(a)(2) of the act, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or the criminal investigator has reasonable grounds to believe that they are, subject to seizure and condemnation under section 304(a)(2) of the act.

(2) Perform such other functions under the act, or any other law, as the Commissioner of Food and Drugs may prescribe.

(3) To administer oaths and affirmations under section 1 of the act of January 31, 1925 (Ch. 124, 43 Stat. 803); sections 12 to 15 of Reorganization Plan No. IV, effective June 30, 1940; and Reorganization Plan No. 1 of 1953, effective April 11, 1953.

(c) Any officer or employee of the Food and Drug Administration who has been designated by the Commissioner to provide specialized law enforcement support involving criminal investigations under the Federal Food, Drug, and Cosmetic Act (the act), and other duties as assigned by the Commissioner, and issued the Food and Drug Administration Official Credential consisting of Form FDA-200E, Special Authority for Criminal Investigative Specialists, is authorized to receive information as to all matters relating to such act and regulations promulgated under the act.

(d) The Food and Drug Administration's official credentials referred to in paragraphs (a), (b), and (c) of this section are described as follows:

(1) Form FDA-200A entitled "Identification Record" bears a color photograph, a description, and the signature of the holder, an identification number, an expiration date, the Department of Health and Human Services' seal with blue imprint, on the left of the photograph, and the Food and Drug Administration's symbol, on the right of the photograph.

(2) Form FDA-200B entitled "Specification of General Authority" bears the holder's name, his or her general

authority, an identification number, an expiration date, the Commissioner's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. The form is superimposed with the Department's seal with blue imprint.

(3) Form FDA-200D, entitled "Special Authority for Criminal Investigators," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under 21 U.S.C. 334 and 372 and other duties as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigator's badge with blue imprint.

(4) Form FDA-200E, entitled "Special Authority for Criminal Investigative Specialists," is in two parts and bears the holder's name, a color photograph, the signature of the holder, his or her special authority under the act, and other duties under the law, as assigned by the Commissioner, an identification number, the Commissioner's or his designee's signature, the names of the Department of Health and Human Services, the Public Health Service, and the Food and Drug Administration. Part 1 of the form is superimposed with the symbol FDA with blue imprint, and part 2 is superimposed with the FDA criminal investigative specialist's badge with blue imprint.

[49 FR 19973, May 11, 1984, as amended at 53 FR 22293, June 15, 1988; 56 FR 23788, May 24, 1991; 58 FR 494, Jan. 6, 1993; 58 FR 42496, Aug. 10, 1993; 59 FR 47799, Sept. 19, 1994]

§ 5.36 Certification following inspections.

Regional Food and Drug Directors and District Directors are authorized to issue certificates of sanitation under § 1240.20 of this chapter.

[60 FR 15871, Mar. 28, 1995]

§ 5.37 Issuance of reports of minor violations.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 309 of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1)(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(2)(i) The Director and Deputy Director of the Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(iii) The Director and Deputy Director, Division of Compliance Operations, Office of Compliance and Surveillance, CDRH.

(iv) The Director, Division of Product Surveillance, Office of Compliance and Surveillance, CDRH.

(3)(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition, (CFSAN).

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Field Programs, CFSAN.

(iv) The Director, Division of Enforcement, Office of Field Programs, CFSAN.

(4)(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(5)(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Director and Deputy Director, Office of Compliance, CDER.

(iii) The Associate Director for Medical Policy, CDER.

(iv) The Director, Division of Drug Marketing, Advertising, and Communications, Office of Drug Evaluation I, Office of Review Management, CDER.

(6)(i) Regional Food and Drug Directors.

(ii) District Directors.

(iii) Chiefs of District Compliance Branches.

(iv) The Director, St. Louis Branch.

(v) The Director, Northeast Regional Laboratory, Northeast Region.

(vi) The Director, Southeast Regional Laboratory, Southeast Region.

(vii) The Director, Winchester Engineering and Analytical Center.

(viii) The Director, National Forensic Chemistry Center.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 539(d) of the Federal Food, Drug, and Cosmetic Act regarding the issuance of written notices or warnings:

(1) The Director and Deputy Director of the Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) Director, Division of Compliance Operations, Office of Compliance and Surveillance, CDRH.

(4) The Director, Division of Standards Enforcement, Office of Compliance and Surveillance, CDRH.

(5) Regional Food and Drug Directors; District Directors; the Director, St. Louis Branch; the Director, Northeast Regional Laboratory, Northeast Region; the Director, Southeast Regional Laboratory, Southeast Region; the Director, Winchester Engineering and Analytical Center; and the Director, National Forensic Chemistry Center, when such functions relate to:

(i) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter; and

(ii) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product as defined in § 1040.20(b) of this chapter.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 14933, 14936, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 59 FR 42491, Aug. 18, 1994; 60 FR 15871, Mar. 28, 1995; 62 FR 2555, Jan. 17, 1997]

§ 5.38 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs, new animal drugs, and feeds bearing or containing new animal drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of written notices.

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Director and Deputy Director, Division of Scientific Investigations, Office of Compliance, CDER.

(7) Regional Food and Drug Directors.

(8) District Directors.

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 512(e) and 512 (m)(4)(B)(ii) and (m)(4)(B)(iii) of the act regarding the issuance of written notices.

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(3) The Director, Division of Compliance, Office of Surveillance and Compliance, CVM.

(4) Regional Food and Drug Directors.

(5) District Directors.

[57 FR 18823, May 1, 1992, as amended at 62 FR 2555, Jan. 17, 1997]

§ 5.39 Redelegation of the Center for Biologics Evaluation and Research Director's program authorities.

The following officials are authorized to perform all the functions of the Director, Center for Biologics Evaluation and Research (CBER) with regard to program authorities for their respective areas:

(a) Associate Directors, CBER.

(b) Office Directors, CBER.

(c) Division Directors, CBER.

[58 FR 18346, Apr. 9, 1993]

§ 5.44 Export of unapproved drugs.

(a) The following officials are authorized, under section 802(b) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove applications to export unapproved new drugs and biological products and to issue notices of receipt of such applications:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For new animal drugs assigned to their respective organizations:

(i) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(b) The following officials are authorized, under section 802(f) of the Federal Food, Drug, and Cosmetic Act, to approve or disapprove an application to export a drug (including a biological product) to be used in the prevention or treatment of a tropical disease:

(1) For human drugs assigned to their respective organizations:

(i) The Director and Deputy Director, CBER.

(ii) The Director and Deputy Director, Office of Compliance, CBER.

(iii) The Director, Deputy Center Director for Review Management, and

Deputy Center Director for Pharmaceutical Science, CDER.

(iv) The Director and Deputy Director, Office of Compliance, CDER.

(2) For veterinary drugs subject to their jurisdiction:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

(c) The following officials are authorized, under section 351(h) of the Public Health Service Act, to approve or disapprove an application to export a partially processed biological product:

(1) The Director and Deputy Director, CBER.

(2) The Director and Deputy Director, Office of Compliance, CBER.

[52 FR 7269, Mar. 10, 1987, as amended at 54 FR 8317, Feb. 28, 1989; 62 FR 2555, Jan. 17, 1997]

§ 5.45 Imports and exports.

(a) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized, under section 801 of the Federal Food, Drug, and Cosmetic Act (FFDCA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of food, drugs (including biological products), devices, or cosmetics imported or offered for import.

(2) Determine whether such articles are in compliance with the FFDCA.

(3) Authorize relabeling or other compliance actions to bring articles into compliance under the FFDCA.

(4) Supervise such compliance actions.

(b) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH); the Director and Deputy Director, Office of Compliance and Surveillance, CDRH; Regional Food and Drug Directors; District Directors; and the Director, St. Louis Branch, are authorized, under section 360 of the Public Health Service Act (PHSA), to perform the following functions or to designate officials to:

(1) Request from the Secretary of the Treasury samples of electronic products imported or offered for import to

determine whether such products are in compliance with the PHSA.

(2) Refuse admission of noncomplying products and notify the Secretary of the Treasury of such refusal.

(3) Supervise operations to bring noncomplying products into compliance under the PHSA.

(4) Refuse or grant permission and time extensions to bring noncomplying products into compliance with the PHSA in accordance with a corrective action plan approved by the Director, Office of Compliance and Surveillance, CDRH.

(c) The following officials are authorized, under section 360B(b) of the PHSA, to exempt persons from issuing a certification, as required by section 358(h) of the PHSA, for electronic products imported into the United States for testing, evaluation, demonstrations, or training, which will not be introduced into commerce and upon completion of their function will be destroyed or exported in accord with U.S. Customs Service's regulations:

(1) The Director and Deputy Director, CDRH.

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) Regional Food and Drug Directors.

(4) District Directors.

(5) The Director, St. Louis Branch.

(d) The Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to exercise all of the functions of the Commissioner of Food and Drugs under section 362 of the PHSA that refers to the prohibition of the introduction of foods, drugs, devices, cosmetics, and electronic products and other items or products regulated by the Food and Drug Administration into the United States when it is determined that it is required in the interest of public health, and such functions relate to the law enforcement functions of the Food and Drug Administration.

(e) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(e) of the FFDCA:

(1) For medical devices assigned to their respective organization:

(i) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(ii) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(iii) The Director and Deputy Director, Division of Compliance Operations, Office of Compliance and Surveillance, CDRH.

(iv) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(v) The Director and Deputy Director, Office of Compliance, CBER.

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 62 FR 2555, Jan. 17, 1997]

§ 5.46 Manufacturer's resident import agents.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, are authorized to reject manufacturer's designations of import agents under § 1005.25(b) of this chapter.

[55 FR 47053, Nov. 9, 1990]

§ 5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(a) For medical devices assigned to their respective organizations:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Office of Compliance, CBER.

(b) Regional Food and Drug Directors.

(c) District Directors.

(d) The Director, St. Louis Branch.

[48 FR 8442, Mar. 1, 1983, as amended at 48 FR 56947, Dec. 27, 1983; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990]

§ 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director

and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989]

§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) and denials of petitions for reclassification of medical devices that are submitted under section 513(e) of the act (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act):

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989]

§ 5.51 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, pursuant to section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, pursuant to section 513 (f)(1)(A) of the act:

(1) The Director and Deputy Director, CDRH, and the Director, Deputy Director, Associate Director, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, CBER.

[55 FR 6974, Feb. 27, 1990, as amended at 60 FR 2014, Jan. 6, 1995]

§ 5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989]

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act:

(i) The Director and Deputy Director, CDRH, and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(ii) The Director and Deputy Director, CBER, and the Director and Deputy Director, Office of Biological Product Review, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Director, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515 (d), (e), and (g) and 520(h)(1) of the act.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 21708, May 23, 1984; 50 FR 9424, Mar. 8, 1985; 54 FR 8317, Feb. 28, 1989]

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40316, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997]

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997]

§ 5.56 Recall authority.

The following officials, for medical devices assigned to their respective organizations, are authorized to perform all of the recall functions under section 518(e) of the Federal Food, Drug, and

Cosmetic Act, which have been delegated to the Commissioner of Food and Drugs:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); and the Director and Deputy Director, Office of Compliance, CDER.

(d) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997]

§ 5.57 Temporary suspension of a medical device application.

The following officials for medical devices assigned to their respective organizations are authorized under section 515(e) of the Federal Food, Drug, and Cosmetic Act, to determine that there is reasonable probability that continuation of the distribution of a device under an approved application would cause serious adverse health consequences or death, and upon making such a determination, to issue an order to temporarily suspend the approval of an application:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(d) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER); the Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER; the Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical

Science, CDER; and the Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

[56 FR 51170, Oct. 10, 1991, as amended at 57 FR 40317, Sept. 3, 1992; 62 FR 2556, Jan. 17, 1997]

§ 5.58 Orphan products.

(a) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized to issue notices, and amendments thereto, inviting sponsorship for orphan products (human and animal drugs, biological products, and medical devices) and submission of:

(1) Notices of claimed investigational exemption for a new drug or new drug applications;

(2) Notices of claimed investigational exemption for a new animal drug or new animal drug applications;

(3) Applications for establishment and product licenses for biological products; or

(4) Applications for an investigational device exemption or premarket approval applications for medical devices, as appropriate.

(b) The Director, Office of Orphan Products Development, Office of the Commissioner, is authorized:

(1) To determine whether there is reason to believe that a drug is a drug for a disease or condition that is rare in the United States under section 525(a) of the Federal Food, Drug, and Cosmetic Act (the act) and to designate such drug as a drug for a rare disease or condition under section 526(a) of the act.

(2) To issue holders of approved applications or licenses notice and opportunity for the submission of views under section 527(b)(1) of the act.

(3) To encourage sponsors of an investigational new drug for a rare disease or condition to design protocols for clinical investigations to permit the addition to the investigation of persons with the disease or condition under section 528 of the act.

(c) The following officials are authorized to provide sponsors, under section

525(a) of the act, with recommendations for nonclinical or clinical investigations believed to be necessary for a drug for a rare disease or condition to be approved or licensed:

(1) For drugs under their jurisdiction:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) For biological products under their jurisdiction:

(i) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(iii) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

[48 FR 40703, Sept. 9, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 27489, July 5, 1984; 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

§ 5.59 Approval, disapproval, or withdrawal of approval of applications for investigational device exemptions.

(a) For medical devices assigned to their respective organizations, the following officials are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH, and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For medical devices assigned to their respective divisions, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of applications for investigational device exemptions submitted under section 520(g) of the act.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14934, Apr. 16, 1984; 54 FR 8318, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990]

§ 5.60 Required and discretionary postmarket surveillance.

(a) For any device (including any device that is or contains a drug or biologic) that was first introduced or delivered for introduction into interstate commerce after January 1, 1991, and that is either a permanent implant, the failure of which may cause serious adverse health consequences or death, a life-sustaining or life-supporting device, or a device that potentially presents a serious risk to human health, any of the following officials is authorized to require a manufacturer of such device to conduct postmarket surveillance:

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Science and Technology, CDRH.

(3) The Director and Deputy Director, Division of Biometric Sciences, Office of Science and Technology, CDRH.

(4) The Director, Deputy Director, Associate Director, Division Directors, and Associate Division Directors, Office of Device Evaluation, CDRH.

(5) The Chief, Premarket Notification Section; Chief, Premarket Approval Section; Director, Program Operations Staff, Office of Device Evaluation, CDRH.

(6) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(7) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(8) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(9) The Director and Deputy Director, Office of Compliance, CDER.

(10) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(11) The Director and Deputy Director, Office of Compliance, CBER.

(12) The Director and Deputy Director, Office of Biological Product Review, CBER.

(b) For any device (including any device that is or contains a drug or biologic), any of the following officials is authorized to require a manufacturer of a device to conduct postmarket surveillance if the official determines that postmarket surveillance of the device is necessary to protect the public health or provide safety or effectiveness data for the device:

(1) The Director and Deputy Director, CDRH.

(2) The Director and Deputy Director, Office of Science and Technology, CDRH.

(3) The Director and Deputy Director, Division of Biometric Sciences, Office of Science and Technology, CDRH.

(4) The Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(5) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(6) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, CDER.

(7) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(8) The Director and Deputy Director, Office of Compliance, CDER, and Drug Evaluation II, CDER.

(9) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(10) The Director and Deputy Director, Office of Compliance, CBER.

(11) The Director and Deputy Director, Office of Biological Product Review, CBER.

[57 FR 40315, Sept. 3, 1992, as amended at 62 FR 2556, Jan. 17, 1997]

§ 5.61 Food standards, food additives, generally recognized as safe (GRAS) substances, color additives, nutrient content claims, and health claims.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) regarding the issuance of notices of filing (including notices of extension of, or reopening of, the comment period), and of voluntary withdrawal, of petitions on food additives, generally recognized as safe (GRAS) substances, and color additives that relate to the assigned functions of the respective Center:

(i) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(ii) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all the functions of the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of proposed rulemaking (including notices of extension of, or reopening of, the comment period) pertaining to food standards.

(b)(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN are authorized to perform all of the functions of the Commissioner of Food and Drugs under sections 409 and 721 of the act regarding the approval of the use of food additives under section 409(e) of the act and the listing of color additives under section 721(d) of the act where the listing does not involve novel or controversial issues and does not involve any questions about the applicability of the Delaney Anti-Cancer Clause.

(2) The following officials are authorized to perform all of the functions of

the Commissioner of Food and Drugs under section 401 of the act regarding the issuance of notices of temporary permits for foods varying from standards of identity under §130.17 of this chapter:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(3) The Director and Deputy Director, CVM, are authorized to perform all the functions of the Commissioner of Food and Drugs regarding approvals of the use of food additives under section 409(e) of the act, where these approvals do not involve novel or controversial issues, including any question about the applicability of the Delaney Anti-Cancer Clause.

(c)(1) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act or to color additive petitions under section 721(d)(1) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Pre-market Approval, CFSAN.

(iv) The Director, Division of Product Policy, Office of Premarket Approval, CFSAN.

(v) The Director, Division of Petition Control, Office of Premarket Approval, CFSAN.

(2) The following officials are authorized to issue 90-day letters to food additive petitioners under section 409(c)(2) of the act that relate to the assigned functions of the Center:

(i) The Director and Deputy Director, CVM.

(ii) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(iii) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to certify batches of color additives under section 721 of the act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Cosmetics and Colors, CFSAN.

(e) The following officials are authorized to issue advance notices of proposed rulemaking pertaining to Codex Alimentarius food standards and notices terminating consideration of such standards when comments fail to support the desirability and need for proposing their adoption, under §130.6 of this chapter:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(f) The following officials are authorized to issue notices of proposed rulemaking and issue or amend regulations affirming generally recognized as safe (GRAS) status of food substances under §170.35 or §570.35 of this chapter where the affirmations relate to the assigned functions of the respective Center and do not involve novel or controversial issues:

(1) The Director and Deputy Directors, CFSAN, and the Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The Director and Deputy Director, CVM.

(g)(1) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs under section 403(r)(4) of the act regarding the issuance of decisions to grant or deny petitions for nutrient content claims and health claims that do not present controversial issues and regarding the issuance of any notices of proposed rulemaking that result from such action:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(2) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs

under section 403(r)(4) of the act regarding the issuing of letters of filing in response to petitions for nutrient content claims and health claims:

(i) The Director and Deputy Directors, CFSAN.

(ii) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(iii) The Director, Office of Food Labeling, CFSAN.

(h) The following officials are authorized to issue letters concerning substances determined to be below the “threshold of regulation” under §170.39 of this chapter:

(1) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(2) The Director, Office of Policy, Planning and Strategic Initiatives, CFSAN.

(3) The Director, Office of Premarket Approval, CFSAN.

(4) The Directors of the Divisions of Petition Control and Product Policy, Office of Premarket Approval, CFSAN.

[49 FR 14936, Apr. 16, 1984, as amended at 49 FR 48183, Dec. 11, 1984; 52 FR 5951, Feb. 27, 1987; 58 FR 2410, Jan. 6, 1993; 59 FR 42492, Aug. 18, 1994; 60 FR 36594, July 17, 1995]

§ 5.62 Issuance of initial emergency permit orders and notices of confirmation of effective date of final regulations on food for human and animal consumption.

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN), the Director, Office of Field Programs, CFSAN, and the Director, Division of Enforcement, Office of Field Programs, CFSAN, are authorized to issue initial emergency permit orders under §108.5 of this chapter.

(b) The following officials are authorized to issue notices of confirmation of effective date of final regulations on food matters promulgated under section 701(e) of the Federal Food, Drug, and Cosmetic Act:

(1) The Director and Deputy Directors, CFSAN.

(2) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(3) The Director, Office of Food Labeling, CFSAN.

(4) The Director, Office of Special Nutritionals, CFSAN.

(5) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

(6) The Director, Office of Seafood, CFSAN.

(7) The Director, Office of Field Programs, CFSAN.

(8) The Director, Office of Premarket Approval, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.63 Detention of meat, poultry, eggs, and related products.

The Regional Food and Drug Directors and District Directors are authorized to perform and to designate other officials to perform all of the functions of the Commissioner of Food and Drugs under:

(a) Section 409(b) of the Federal Meat Inspection Act (21 U.S.C. 679(b)) which relate to the detention of any carcass, part thereof, meat, or meat product of cattle, sheep, swine, goats, or equines.

(b) Section 24(b) of the Poultry Products Inspection Act (21 U.S.C. 467f(b)) which relate to the detention of any poultry carcass, part thereof, or poultry product.

(c) The Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

[48 FR 8442, Mar. 1, 1983, as amended at 54 FR 9034, Mar. 3, 1989; 60 FR 15871, Mar. 28, 1995]

§ 5.64 Establishing standards and approving accrediting bodies under the National Laboratory Accreditation Program.

The Director and Deputy Director, Center for Food Safety and Applied Nutrition, are authorized to perform all the functions of the Commissioner of Food and Drugs under sections 1322(b) and (c) of the Food, Agriculture, Conservation, and Trade Act of 1990 (the National Laboratory Accreditation Program) (7 U.S.C. 138a), as amended hereafter; which relate to setting standards for the National Laboratory Accreditation Program and approving State agencies or private, nonprofit entities as accrediting bodies to implement certification and quality assurance programs in accordance with the requirements of these sections. The

delegation excludes the authority to submit reports to the Congress.

[57 FR 43398, Sept. 21, 1992]

§ 5.66 Approval of schools providing food-processing instruction.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 113.10 of this chapter regarding the approval of schools giving instruction in retort operations, processing systems operations, aseptic processing and packaging system operations, and container closure inspections:

(a) The Director and Deputy Directors, Center for Food Safety and Applied Nutrition (CFSAN).

(b) The Director, Office of Policy, Planning, and Strategic Initiatives, CFSAN.

(c) The Director, Office of Plant and Dairy Foods and Beverages, CFSAN.

[59 FR 42492, Aug. 18, 1994]

§ 5.67 Issuance of notices of opportunity for a hearing on proposals for denial of approval of applications for licenses or revocation of licenses and certain notices of revocation of licenses.

The Director and Deputy Director, Center for Biologics Evaluation and Research are authorized to issue:

(a) Notices of opportunity for a hearing on proposals to deny approval or filing of applications for establishment or product licenses under § 601.4(b) of this chapter.

(b) Notices of opportunity for a hearing on proposals to revoke establishment or product licenses under § 601.5(b) of this chapter.

(c) Notices of revocation, at the manufacturer's request, of establishment or product licenses under §§ 601.5(a) and 601.8 of this chapter.

(d) Notices of revocation when the manufacturer has waived the opportunity for hearing under § 601.7(a) of this chapter.

[50 FR 30697, July 29, 1985, as amended at 54 FR 8318, Feb. 28, 1989; 56 FR 25025, June 3, 1991]

§ 5.68 Issuance and revocation of licenses for the propagation or manufacture and preparation of biological products.

The following officials are authorized to issue licenses under section 351 of the Public Health Service Act (42 U.S.C. 262) for the propagation or manufacture and preparation of biological products as specified in the act, and to revoke such licenses at the manufacturer's request:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8318, Feb. 28, 1989]

§ 5.69 Notification of release for distribution of biological products.

The following officials are authorized to issue written notices of release for distribution of licensed biological products under subchapter F (parts 600 through 699) of this chapter:

(a) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The Director and Deputy Director, Office of Biological Product Review, CBER.

(c) The Director and Deputy Director, Division of Product Quality Control, Office of Biological Product Review, CBER.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 19341, May 8, 1985; 54 FR 8318, Feb. 28, 1989]

§ 5.70 Issuance of notice implementing the provisions of the Drug Amendments of 1962.

The Director, Deputy Center Director for Review Management, and Deputy Director, Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices and amendments thereto implementing section 107(c)(3) of the Drug Amendments of 1962 (Pub. L. 87-781) by announcing new or revised efficacy findings on human drugs that are or were subject to the

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provisions of sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act.

[62 FR 2556, Jan. 17, 1997]

§ 5.71 Termination of exemptions for new drugs for investigational use in human beings and in animals.

(a) The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs on the termination of exemptions for new drugs (including those that are biological products which are subject to the licensing provisions of the Public Health Service Act) for investigational use in human beings under § 312.44 of this chapter and in animals under § 312.160 of this chapter:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The following officials, for drugs under their jurisdiction, are authorized to terminate exemptions for new drugs for investigational use when sponsors fail to submit an annual progress report under § 312.44(b)(1)(viii) of this chapter:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(c) The following officials, for drugs under their jurisdiction, are authorized to make the findings set forth in § 312.44(b) of this chapter and to notify sponsors and invite correction before termination action on such exemptions:

(1) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

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(2) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Director and Deputy Director, Office of Biological Product Review, CBER.

(4) The Director and Deputy Director, Division of Biological Investigational New Drugs, Office of Biological Product Review.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with regard to the termination of new animal drugs for investigational use in animals under § 511.1 of this chapter:

(1) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(2) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[49 FR 14934, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 52 FR 7829, Mar. 13, 1987; 54 FR 8318, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2556, Jan. 17, 1997]

§ 5.72 Authority to approve and to withdraw approval of a charge for investigational new drugs.

The following officials, for drugs under their jurisdiction, are authorized to perform all the functions of the Commissioner of Food and Drugs to approve a charge and to withdraw approval to charge for investigational drugs in a clinical trial under an investigational new drug application under § 312.7(d)(1) of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

[55 FR 5445, Feb. 15, 1990, as amended at 62 FR 2556, Jan. 17, 1997]

§ 5.73 Certification of insulin.

The following officials are authorized to certify or reject batches of drugs containing insulin pursuant to section 506(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director, Deputy Center Director for Review Management, and

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

(e) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(f) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2556, Jan. 17, 1997]

§ 5.74 Issuance, amendment, or repeal of regulations pertaining to drugs containing insulin.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 506 of the Federal Food, Drug, and Cosmetic Act regarding the issuance, amendment, or repeal of regulations pertaining to drugs containing insulin:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director, Office of Drug Evaluation II, Office of Review Management, CDER.

(c) The Director and Deputy Director, Division of Metabolism and Endocrine Drug Products, Office of Drug Evaluation II, Office of Review Management, CDER.

(d) The Director and Deputy Director, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.75 Designation of official master and working standards for antibiotic drugs.

The following officials are authorized to designate official Food and Drug Administration master and working standards for antibiotic drugs under § 430.5 of this chapter:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

(c) The Director and Deputy Director, Division of Research and Testing, Office of Testing and Research, Office of Pharmaceutical Science, CDER.

[49 FR 27315, July 3, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.76 Certification of antibiotic drugs.

The following officials are authorized to certify or reject batches of antibiotic drugs, or any derivative of these drugs, pursuant to sections 507(a) and 512(n) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Office of Compliance, CDER.

(c) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(d) The Team Leader and Assistant, Post-Marketing Surveillance Team, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

[49 FR 14934, Apr. 16, 1984, as amended at 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.78 Issuance, amendment, or repeal of regulations pertaining to antibiotic drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) regarding

the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director, Office of Drug Evaluation I, Office of Review Management, CDER.

(3) The Director, Office of Drug Evaluation IV, Office of Review Management, CDER.

(4) The Director and Deputy Director, Division of Oncologic Drug Products, Office of Drug Evaluation I, Office of Review Management, CDER.

(5) The Director and Deputy Director, Division of Anti-Infective Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

(6) The Director and Deputy Director, Division of Anti-Viral Drug Products, Office of Drug Evaluation IV, Office of Review Management, CDER.

(7) The Director and Deputy Director, Office of Compliance, CDER.

(b) The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to perform all the functions of the Commissioner of Food and Drugs under section 507 of the act regarding the issuance, amendment, or repeal of regulations pertaining to antibiotic drugs for human use contained in medical devices.

[48 FR 56948, Dec. 27, 1983, as amended at 49 FR 14935, Apr. 16, 1984; 54 FR 8319, Feb. 28, 1989; 62 FR 2557, Jan. 17, 1997]

§ 5.80 Approval of new drug applications and their supplements.

(a)(1) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act:

(i) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), for drugs listed in § 314.440(b) of this chapter, are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act.

(b) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER, for drugs under their jurisdiction, are authorized to perform all functions of the Commissioner of Food and Drugs with regard to approval of supplemental applications to approved new drug applications for drugs for human use that have been submitted under § 314.70 of this chapter and of new drug applications for drug products other than those that contain new molecular entities (new chemical entities). The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to approval of abbreviated new drug applications and supplements thereto for drugs for human use and new drug applications for drugs with a 5S classification whose clinical safety and efficacy may be supported by appropriate literature citations in lieu of submission of data from original proprietary studies, or 505(b)(2) applications under their jurisdiction. The applications to which this authorization applies may, in appropriate circumstances, continue to be acted upon by the officials so authorized in § 5.10(a) and paragraph (a) of this section.

(1) For drugs submitted under §§ 314.50, 314.70, and 314.94 of this chapter, except for those drug products listed in § 314.440(b):

(i) The Director and Deputy Director, Office of Generic Drugs (OGD), Office of

Pharmaceutical Science, CDER, except that the Director and Deputy Director, OGD are not authorized to approve new drug applications with a 5S classification if clinical studies are needed.

(ii) The Directors and Deputy Directors of the divisions in Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(2)(i) For drug products listed in § 314.440(b) and submitted under §§ 314.50, 314.70, and 314.94 of this chapter:

(ii) The Director and Deputy Director, Office of Biological Product Review, CBER.

(d) The following officials are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or that include in vivo bioavailability study waiver requests are not included in this paragraph.

(1) The Director and Deputy Director, Division of Chemistry I, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(2) The Director and Deputy Director, Division of Chemistry II, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(3) Associate Director for Chemistry, Office of Pharmaceutical Science, CDER.

(e) The Director, Division of Labeling and Program Support, Office of Generic Drugs, Office of Pharmaceutical Science, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to abbreviated new drug applications, 5S applications, or 505(b)(2) applications for drugs for human use that are described in §§ 314.70(b)(3) and (c)(2)(i) through (c)(2)(iv) of this chapter. Authority to approve supplements that require in vivo bioavailability studies or in vivo study waiver re-

quests is not included in this paragraph.

(f) The supervisory and team leader chemists in the Divisions of New Drug Chemistry I, II, and III, Office of New Drug Chemistry, Office of Pharmaceutical Science, CDER, are authorized to perform all functions of the Commissioner of Food and Drugs with respect to approval of supplemental applications to new drug applications for drugs for human use that are described in §§ 314.70(b)(1), (b)(2)(ii) through (b)(2)(x), (c)(1), and (c)(3) of this chapter. Authority to approve supplements that require in vivo bioavailability information or that require a change in the labeling of the drug, except changes that reflect only the use of a different facility or establishment, are not included in this paragraph. The supplemental applications to which this authorization applies may continue to be acted upon by the officials so authorized in § 5.10(a) and paragraphs (a) and (b) of this section.

[49 FR 14935, Apr. 16, 1984, as amended at 50 FR 30697, July 29, 1985; 50 FR 47207, Nov. 15, 1985; 52 FR 37764, Oct. 9, 1987; 54 FR 8319, Feb. 28, 1989; 55 FR 6247, Feb. 22, 1990; 55 FR 51688, Dec. 17, 1990; 57 FR 17980, Apr. 28, 1992; 58 FR 17094, Apr. 1, 1993; 59 FR 33431, June 29, 1994; 60 FR 57338, Nov. 15, 1995; 62 FR 2557, Jan. 17, 1997]

§ 5.81 Responses to Drug Enforcement Administration temporary scheduling notices.

The Associate Commissioner for Health Affairs is authorized to provide responses to the Drug Enforcement Administration's temporary scheduling notices under the Controlled Substances Act, as amended (Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. 811(h)(4), as amended hereafter). The delegation excludes the authority to submit reports to Congress.

[60 FR 54424, Oct. 24, 1995]

§ 5.82 Issuance of notices relating to proposals to refuse approval or to withdraw approval of new drug applications and their supplements.

(a) The Director, Deputy Center Director for Review Management, and

Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER), are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use, except for those drugs listed in § 314.440(b) of this chapter, that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research, for those drugs listed in § 314.440(b) of this chapter, are authorized to issue notices of an opportunity for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the Federal Food, Drug, and Cosmetic Act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

[54 FR 8319, Feb. 28, 1989, as amended at 62 FR 2558, Jan. 17, 1997]

§ 5.83 Approval of new animal drug applications and their supplements.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of new animal drug applications, and supplements thereto, for new animal drugs submitted pursuant to section 512 of the Federal Food, Drug, and Cosmetic Act (the act).

(b) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to approved new animal drugs submitted pursuant to section 512 of the act:

(1) The Director, the Deputy Director for Human Food Safety and Consult-

ative Services, and the Deputy Director for Therapeutic and Production Drug Review, Office of New Animal Drug Evaluation, CVM.

(2) The Director and Deputy Director, Office of Surveillance and Compliance, CVM.

(c) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of supplemental applications to new animal drug applications that are described by § 514.8(a)(4)(iii), (iv), and (v), and (d)(3) of this chapter.

(1) The Director, Division of Chemistry, Office of New Animal Drug Evaluation, CVM.

(2) The Director, Division of Surveillance, Office of Surveillance and Compliance, CVM.

(d) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to the approval of applications for animal feeds containing new animal drugs:

(1) The Director and Deputy Director, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(2) The Chief, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

(3) The Medicated Feeds Specialist, Petition Review and Medicated Feeds Branch, Division of Animal Feeds, Office of Surveillance and Compliance, CVM.

[49 FR 14937, Apr. 16, 1984, as amended at 50 FR 14094, Apr. 10, 1985; 53 FR 2225, Jan. 27, 1988; 53 FR 17186, May 16, 1988; 53 FR 40055, Oct. 13, 1988]

§ 5.84 Issuance of notices, proposals, and orders relating to new animal drugs and feeds bearing or containing new animal drugs.

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM), are authorized to:

(1) Issue notices of opportunity for a hearing on proposals to refuse approval or to withdraw approval of new animal drug applications, and supplements thereto, for drugs for animal use and feeds bearing or containing new animal drugs, submitted pursuant to section

512 of the Federal Food, Drug, and Cosmetic Act;

(2) Issue notices refusing or withdrawing approval when opportunity for hearing has been waived; and

(3) Issue proposals and orders to revoke and amend regulations for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs, corresponding to said action on such applications.

(b) The Director and Deputy Director, CVM, are authorized to issue notices of availability of Public Master Files containing data acceptable for use in applications for new animal drugs for drugs for animal use and feeds bearing or containing new animal drugs.

[49 FR 17936, Apr. 26, 1984]

§ 5.85 Authority to ensure that mammography facilities meet quality standards.

(a) The following officials are authorized to issue, renew, and extend certificates to mammography facilities under section 354(c) of the Public Health Service Act (42 U.S.C. 263b):

(1) The Director and Deputy Director for Regulations and Policy, Center for Devices and Radiological Health (CDRH).

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(b) The following officials are authorized to accept an application for a certificate under section 354(d)(1) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(c) The following officials are authorized to approve accreditation bodies to accredit mammography facilities under section 354(e)(1)(A) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(d) The following officials are authorized to ensure that accreditation bodies provide satisfactory assurances of compliance under section 354(e)(1)(C) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(e) The Director, CDRH, is authorized to promulgate regulations under which the Director may withdraw approval of accreditation bodies under section 354(e)(2) of the Public Health Service Act.

(f) The following officials are authorized to determine the applicable standards for a facility for accreditation under section 354(e)(3) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(g) The following officials are authorized to ensure that accreditation bodies make on site visits and to determine whether other measures are appropriate under section 354(e)(4)(A) and (e)(4)(B) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(h) The following officials are authorized to evaluate annually the performance of each approved accreditation body as provided by section 354(e)(6)(A) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(i) The following officials are authorized to determine the compliance of certified facilities with established standards through facility inspections as provided by section 354(g) of the Public Health Service Act:

(1) The Director and Deputy Director for Regulations and Policy, CDRH.

(2) The Director, Office of Health and Industry Programs, CDRH.

(3) The Director, Division of Mammography Quality and Radiation Programs, Office of Health and Industry Programs, CDRH.

(j) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to impose sanctions under section 354(h)(1) and (h)(2) of the Public Health Service Act.

(k) The Director and Deputy Director for Regulations and Policy, CDRH, are authorized to suspend or revoke individual facility certificates under section 354(i)(1) and (i)(2)(A) of the Public Health Service Act.

(l) The Director and Deputy Director for Regulations Policy, CDRH, are authorized to compile and make available to physicians and the general public information the Director determines is useful in evaluating the performance of mammography facilities as provided by section 354(l) of the Public Health Service Act.

(m)(1) The following officials may authorize a State to carry out certification program requirements and implement quality standards under section 354(q)(1) and (q)(2) of the Public Health Service Act:

(i) The Director and Deputy Director for Regulations and Policy, CDRH.

(ii) The Director, Office of Health and Industry Programs, CDRH.

(2) The Director, CDRH, is authorized, after providing notice and opportunity for corrective action, to withdraw the approval of a State's authority to carry out certification requirements and implement quality standards under section 354(q)(4) of the Public Health Service Act.

[60 FR 47268, Sept. 12, 1995]

§ 5.86 Variances from performance standards for electronic products.

The following officials are authorized to grant and withdraw variances and issue notices of availability of any approved variance or any amendment or extension thereof, from the provisions of performance standards for electronic products established in subchapter J of this chapter:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990]

§ 5.87 Exemption of electronic products from performance standards and prohibited acts.

The following officials are authorized to exempt from performance standards any electronic product intended for use by departments or agencies of the United States under section 358(a)(5) of the Public Health Service Act (the act) and to exempt an electronic product or class of products from all or part of the provisions of section 360B(a) of the act under section 360B(b) of that act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH).

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(c) The Director and Deputy Director, Office of Standards and Regulations, CDRH.

[52 FR 29664, Aug. 11, 1987, as amended at 55 FR 47053, Nov. 9, 1990]

§ 5.88 Testing programs and methods of certification and identification for electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, are authorized to review and evaluate industry testing programs under section 358(g) of the Public Health Service Act (the

act), and to approve or disapprove alternate methods of certification and identification and to disapprove testing programs upon which certification is based under section 358(h) of the act.

[55 FR 47054, Nov. 9, 1990]

§ 5.89 Notification of defects in, and repair or replacement of, electronic products.

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, are authorized to perform all functions of the Commissioner of Food and Drugs, relating to notification of defects in, noncompliance of, and repair or replacement of or refund for, electronic products under section 359 of the Public Health Service Act (the act) and under §§ 1003.11, 1003.22, 1003.31, 1004.2, 1004.3, 1004.4, and 1004.6 of this chapter; and Regional Food and Drug Directors, District Directors, and the Director, St. Louis Branch, are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp product, as defined in § 1040.20(b) of this chapter.

(b) The Director and Deputy Director, Office of Compliance and Surveillance, CDRH, and the Director, Division of Standards Enforcement, Office of Compliance and Surveillance, CDRH, are authorized to notify manufacturers of defects in, and noncompliance of, electronic products under section 359(e) of the act and under § 1003.11(a) of this chapter; and the chiefs of District Compliance Branches are authorized to perform all such functions relating to:

(1) Assemblers of diagnostic x-ray systems, as defined in § 1020.30(b) of this chapter.

(2) Manufacturers of sunlamp products and ultraviolet lamps intended for use in any sunlamp products, as defined in § 1040.20(b) of this chapter.

[48 FR 56948, Dec. 27, 1983, as amended at 51 FR 32452, Sept. 12, 1986; 55 FR 47054, Nov. 9, 1990; 62 FR 15110, Mar. 31, 1997]

§ 5.90 Manufacturers requirement to provide data to ultimate purchasers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to require manufacturers to provide performance and technical data to the ultimate purchaser of electronic products under section 360A(c) of the Public Health Service Act.

[48 FR 56948, Dec. 27, 1983]

§ 5.91 Dealer and distributor direction to provide data to manufacturers of electronic products.

The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), the Director and Deputy Director, Office of Compliance and Surveillance, CDRH, and the Director, Division of Standards Enforcement, Office of Compliance and Surveillance, CDRH, are authorized to direct dealers and distributors of electronic products to furnish information on first purchasers of such products to the manufacturer of the product under section 360A(f) of the Public Health Service Act.

[55 FR 47054, Nov. 9, 1990]

§ 5.92 Acceptance of assistance from State and local authorities for enforcement of radiation control legislation and regulations.

The Director and Deputy Director, Center for Devices and Radiological Health, are authorized to accept assistance from State and local authorities engaged in activities related to health or safety or consumer protection on a reimbursable basis or otherwise, under section 360E of the Public Health Service Act.

[48 FR 56949, Dec. 27, 1983]

§ 5.93 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) of the Federal Food, Drug and Cosmetic Act (the act) concerning the date of

submission or the date or effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act and of new drug applications including supplements thereto submitted under section 505(b)(1) of the act and described under section 505(b)(2) of the act:

(a) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(b) The Director and Deputy Director, Division of Bioequivalence, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

[53 FR 18274, May 23, 1988, as amended at 55 FR 6247, Feb. 22, 1990; 62 FR 2558, Jan. 17, 1997]

§ 5.94 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(a) For drugs assigned to their organizations:

(1) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(2) The Director and Deputy Director, Office of Biological Product Review, CBER.

(3) The Directors and Deputy Directors of the divisions in the Office of Biological Product Review, CBER.

(b) For drugs assigned to their organizations:

(1) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(3) The Directors and Deputy Directors of the divisions in the Offices of

Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

[52 FR 2514, Jan. 23, 1987, as amended at 54 FR 8320, Feb. 28, 1989; 55 FR 51688, Dec. 17, 1990; 62 FR 2558, Jan. 17, 1997]

§ 5.95 Submission of and effective approval dates for abbreviated new animal drug applications and certain new animal drug applications.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs with regard to decisions made under section 512(c)(2)(D)(iv) and (c)(2)(F) of the Federal, Food, Drug, and Cosmetic Act (the act) concerning the date of submission and the date of effective approval of abbreviated new animal drug applications including supplements thereto, submitted under section 512(b)(2) of the act, and of new animal drug applications including supplements thereto, submitted under section 512(b)(1) of the act:

(a) The Director and Deputy Director, Center for Veterinary Medicine (CVM).

(b) The Director and Deputy Director, Office of New Animal Drug Evaluation, CVM.

[56 FR 6263, Feb. 15, 1991]

§ 5.98 Authority relating to medical device reporting procedures.

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to approve electronic reporting under § 803.14 of this chapter.

(b) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to request the submission of additional information under § 803.15 of this chapter.

(c) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Surveillance and Biometrics, CDRH, are authorized to grant or revoke exemptions

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and variances from reporting requirements under § 803.19 of this chapter.

[60 FR 63607, Dec. 11, 1995]

§ 5.99 Issuance of notices relating to proposals and orders for debarment and denial of an application to terminate debarment.

The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), the Director and Deputy Director, Center for Veterinary Medicine (CVM), and the Director and Associate Director for Policy Coordination and Public Relations, Center for Biologics Evaluation and Research (CBER) are authorized to issue the following notices under section 306 of the Federal Food, Drug, and Cosmetic Act (the act) which relate to the assigned functions of their organizations:

(a) Notices of opportunity for hearing on proposals for mandatory or permissive debarment.

(b) Notices ordering debarment when opportunity for a hearing has been waived.

(c) Notices ordering debarment where the person notifies the agency that the person acquiesces to debarment under section 306(c)(2)(B) of the act.

(d) Notices of opportunity for hearing on proposals denying an application to terminate debarment under section 306(d)(3) of the act.

(e) Orders denying an application to terminate debarment under section 306(d)(3) of the act when opportunity for a hearing has been waived.

[61 FR 8215, Mar. 4, 1996; 61 FR 11545, Mar. 21, 1996; 61 FR 14375, Apr. 1, 1996]

Subpart C—Organization

§ 5.200 Headquarters.

The central organization of the Food and Drug Administration consists of the following:

OFFICE OF THE COMMISSIONER.¹
OFFICE OF THE ADMINISTRATIVE LAW JUDGE.

OFFICE OF EXECUTIVE SECRETARIAT.

OFFICE OF EQUAL EMPLOYMENT AND CIVIL RIGHTS.

OFFICE OF THE CHIEF COUNSEL.

OFFICE OF INTERNAL AFFAIRS.

OFFICE OF EXTERNAL AFFAIRS.

Industry and Small Business Liaison Staff.
Office of Special Health Issues.
Office of Consumer Affairs.
Office of Health Affairs.
Office of Legislative Affairs.
Office of Public Affairs.
Office of Women's Health.
Office of International Affairs.

OFFICE OF MANAGEMENT AND SYSTEMS.

Office of Planning and Evaluation.
Office of Human Resources and Management Services.
Office of Facilities, Acquisitions, and Central Services.
Office of Information Resources Management.
Office of Financial Management.

OFFICE OF POLICY.

Regulations Policy and Management Staff.
Policy Development and Coordination Staff.
Policy Research Staff.
International Policy Staff.

OFFICE OF OPERATIONS.

OFFICE OF SCIENCE.

OFFICE OF ORPHAN PRODUCTS DEVELOPMENT.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH.²

Office of the Center Director

Environmental Health and Program Assurance Staff.
Equal Employment Opportunity Staff.
Scientific Coordination Staff.
Technology Advancement Staff.

Office of Planning and Resource Management

Planning Staff.
Financial Management Staff.
Evaluation Staff.

Office of Research

Research Coordination Staff.
Biomarkers Laboratory Staff.

¹Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

²Mailing address: Jefferson, AR 72079-9502.

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Division of Reproductive and Developmental Toxicology.
Division of Genetic Toxicology.
Division of Biochemical Toxicology.
Division of Nutritional Toxicology.
Division of Biometry and Risk Assessment.
Division of Chemistry.
Division of Microbiology.
Division of Neurotoxicology.

Office of Research Support

Veterinary Services Staff.
Information Technology Staff.
Division of Administrative Services.
Division of Facilities Engineering and Maintenance.

OFFICE OF REGULATORY AFFAIRS.³

Office of the Associate Commissioner

Contaminants Policy Coordination Staff.
Equal Employment Opportunity Staff.
Strategic Initiatives Staff.

Office of Resource Management

Division of Planning, Evaluation, and Management.
Division of Information Systems.
Division of Human Resource Development.
Division of Management Operations.

Office of Enforcement

Medical Products Quality Assurance Staff.
Division of Compliance Management and Operations.
Division of Compliance Policy.

Office of Regional Operations

Division of Federal-State Relations.
Division of Field Science.
Division of Emergency and Investigational Operations.
Division of Import Operations and Policy.

Office of Criminal Investigations⁴

Northeast Regional Office.⁵
Mid-Atlantic Regional Office.⁶
Southeast Regional Office.⁷
Midwest Regional Office.⁸
Southwest Regional Office.⁹

³Mailing address: 5600 Fishers Lane, Rockville, MD 20857.

⁴Mailing address: 7500 Standish Pl., rm. 250N, Rockville, MD 20855.

⁵Mailing address: 850 Third Ave., Brooklyn, NY 11232.

⁶Mailing address: 900 U. S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

⁷Mailing address: 60 Eighth St. NE., Atlanta, GA 30309.

⁸Mailing address: 20 North Michigan Ave., Chicago, IL 60606.

⁹Mailing address: 7920 Elmbrook Dr., Dallas, TX 75247.

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Pacific Area Office.¹⁰

CENTER FOR BIOLOGICS EVALUATION AND RESEARCH.¹¹

Office of the Center Director

Equal Employment Opportunity Staff.
Scientific Advisors and Consultants Staff.
Quality Assurance Staff.
Congressional and Public Affairs Staff.

Office of Communication, Training and Manufacturers Assistance

Division of Congressional and Public Affairs.
Division of Manufacturers Assistance and Training.

Office of Management

Division of Management Services.
Division of Applied Information Technology.
Division of Planning, Evaluation, and Budget.

Office of Compliance

Division of Case Management.
Division of Regulations and Policy.
Division of Inspections and Surveillance.

Office of Therapeutics Research and Review

Division of Cytokine Biology.
Division of Cellular and Gene Therapies.
Division of Hematologic Products.
Division of Monoclonal Antibodies.
Division of Clinical Trial Design and Analysis.
Division of Application Review and Policy.

Office of Vaccines Research and Review

Division of Allergenic Products and Parasitology.
Division of Bacterial Products.
Division of Viral Products.
Division of Vaccines and Related Products Applications.

Office of Establishment Licensing and Product Surveillance

Division of Product Quality Control.
Division of Veterinary Services.
Division of Biostatistics and Epidemiology.
Division of Establishment Licensing.
Division of Congressional Public Affairs.

Office of Blood Research and Review

Division of Blood Applications.
Division of Transfusion Transmitted Diseases.
Division of Hematology.
Division of Blood Establishment & Products.

¹⁰Mailing address: 13301 Clay St., Oakland, CA 94512.

¹¹Mailing address: 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448.

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CENTER FOR DRUG EVALUATION AND RESEARCH.¹²

Office of the Center Director

Advisors and Consultants Staff.
Pilot Drug Evaluation Staff.
Executive Operations Staff.
Equal Employment Opportunity Staff.
Regulatory Policy Staff.

Office of Management

Administrative Staff.
Division of Planning, Evaluation, and Resource Management.
Division of Management Services.
Division of Information Systems Design.
Division of Database Management.

Office of Training and Communications

Freedom of Information Staff.
Division of Training and Development.
Division of Communications Management.
Division of the Medical Library.

Office of Compliance

Division of Labeling and Nonprescription Drug Compliance.
Division of Prescription Drug Compliance and Surveillance.
Division of Manufacturing and Product Quality.
Division of Scientific Investigations.

Office of Pharmaceutical Science

Office of the Director

Product Quality Support Staff.
Operations Staff.

Office of New Drug Chemistry

Division of New Drug Chemistry I.
Division of New Drug Chemistry II.
Division of New Drug Chemistry III.

Office of Generic Drugs¹³

Division of Chemistry I.
Division of Chemistry II.
Division of Bioequivalence.
Division of Labeling and Program Support.

Office of Clinical Pharmacology and Biopharmaceutics

Division of Pharmaceutical Evaluation I.
Division of Pharmaceutical Evaluation II.
Division of Pharmaceutical Evaluation III.

Office of Testing and Research

Laboratory of Clinical Pharmacology.
Regulatory Research and Analysis Staff.

Division of Product Quality Research.
Division of Applied Pharmacology Research.
Division of Testing and Applied Analytical Development.

Office of Review Management

Office of the Director

Advisors and Consultants Staff.

Office of Drug Evaluation I

Division of Neuropharmacological Drug Products.
Division of Oncology Drug Products.
Division of Cardio-Renal Drug Products.
Division of Drug Marketing, Advertising and Communication.

Office of Drug Evaluation II

Division of Metabolic and Endocrine Drug Products.
Division of Pulmonary Drug Products.

Office of Drug Evaluation III

Division of Gastrointestinal and Coagulation Drug Products.
Division of Anesthetic, Critical Care, and Addiction Drug Products.
Division of Medical Imaging and Radiopharmaceutical Drug Products.

Office of Drug Evaluation IV

Division of Anti-Infective Drug Products.
Division of Anti-Viral Drug Products.

Office of Drug Evaluation V

Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products.
Division of Dermatologic and Dental Drug Products.
Division of Over-The-Counter Drug Products.

Office of Epidemiology and Biostatistics

Quantitative Methods and Research Staff.
Division of Pharmacovigilance and Epidemiology.
Division of Biometrics I.
Division of Biometrics II.
Division of Biometrics III.
Division of Biometrics IV.

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH.¹⁴

Office of the Center Director

Equal Employment Opportunity Staff.

Office of Systems and Management

Integrity, Committee and Conference Management Staff.
Division of Management Operations.
Division of Information Dissemination.

¹² Mailing address: 1451 Rockville Pike, rm. 6027, Rockville, MD 20850.

¹³ Mailing address: 7500 Standish Pl., rm. 286, Rockville, MD 20855.

¹⁴ Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

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Division of Information Technology Management.
Division of Planning, Analysis and Finance

Office of Health and Industry Programs¹⁵

Division of Device User Programs and Systems Analysis.
Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.
Program Operations Staff.

Office of Compliance¹⁶

Promotion and Advertising Policy Staff.
Division of Program Operations.
Division of Bioresearch Monitoring.
Division of Enforcement I.
Division of Enforcement II.
Division of Enforcement III.

Office of Device Evaluation¹⁷

Program Operations Staff.
Program Management Staff.
Division of Cardiovascular, Respiratory, and Neurological Devices.
Division of Reproductive, Abdominal, Ear, Nose, and Throat, and Radiological Devices.
Division of General and Restorative Devices.
Division of Clinical Laboratory Devices.¹⁸
Division of Ophthalmic Devices.
Division of Dental, Infection Control, and General Hospital Devices.

Office of Science and Technology¹⁹

Division of Mechanics and Materials Science.
Division of Life Sciences.
Division of Physical Sciences.
Division of Electronics and Computer Sciences.
Division of Management, Information, and Support Services.

Office of Surveillance and Biometrics²⁰

Division of Biostatistics.
Division of Postmarket Surveillance.
Division of Surveillance Systems.

Office of Health and Industry Programs

Division of Device User Programs and Systems Analysis.

¹⁵ Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

¹⁶ Mailing address: 2098 Gaither Rd., Oak Grove Corporate Park, Rockville, MD 20850.

¹⁷ Mailing address: 9200 Corporate Blvd., Rockville, MD 20850.

¹⁸ Mailing address: 2098 Gaither Rd., Rockville, MD 20850.

¹⁹ Mailing address: 12720 Twinbrook Pkwy., Bldg. 1, Rockville, MD 20857.

²⁰ Mailing address: 1350 Piccard Dr., Rockville, MD 20850.

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Division of Small Manufacturers Assistance.
Division of Mammography Quality and Radiation Programs.
Division of Communication Media.

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION.²¹

Office of the Center Director

Equal Employment Opportunity Staff.

Office of Beltsville Technical Operations

Office of Policy, Planning and Strategic Initiatives

Executive Operations Staff.

Office of Programs

Beltsville Technical Operations Staff.

Office of Cosmetics and Colors

Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Food Labeling

Division of Programs and Enforcement Policy.
Division of Technical Evaluation.
Division of Science and Applied Technology.

Office of Premarket Approval

Division of Product Policy.
Division of Petition Control.
Division of Health Effects Evaluation.
Division of Molecular Biological Research and Evaluation.
Division of Product Manufacture and Use.

Office of Plant and Dairy Foods and Beverages

Division of Programs and Enforcement Policy.
Division of Virulence Assessment.
Division of Pesticides and Industrial Chemicals.
Division of Natural Products.
Division of Food Processing and Packaging.

Office of Seafood

Division of Special Programs.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Special Nutritionals

Clinical Research and Review Staff.
Division of Programs and Enforcement Policy.
Division of Science and Applied Technology.

Office of Special Research Skills

Division of Toxicology Research.

²¹ Mailing address: 200 C St. SW., Washington, DC 20204.

Food and Drug Administration, HHS

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Division of Microbiological Studies.

Office of Systems and Support

Quality Assurance Staff.

Office of Constituent Operations

Consumer Education Staff.

Legislative Activities Staff.

Industry Activities Staff.

International Activities Staff.

Office of Field Programs

Division of Enforcement.

Division of HACCP Programs.

Division of Cooperative Programs.

Division of Field Program Planning and Evaluation.

Office of Management Systems

Safety Management Staff.

Division of Information Resources Management.

Division of Planning and Resources Management.

Office of Scientific Analysis and Support

Division of Mathematics.

Division of General Scientific Support.

Division of Market Studies.

CENTER FOR VETERINARY MEDICINE.²²

Office of the Center Director

Office of Management and Communications

Administrative Staff.

Communications Staff.

Program Planning and Evaluation Staff.

Information Resources Management Staff.

Office of Surveillance and Compliance

Division of Compliance.

Division of Animal Feeds.

Division of Epidemiology and Surveillance.

Office of New Animal Drug Evaluation

Division of Biometrics and Production Drugs.

Division of Manufacturing Technologies.

Division of Therapeutic Drugs for Food Animals.

Division of Therapeutic Drugs for Non-Food Animals.

Division of Human Food Safety.

Office of Research

Administrative Staff.

Division of Residue Chemistry.

Division of Animal Research.

[62 FR 13822, Mar. 24, 1997]

²² Mailing address: 7500 Standish Pl., MPN-2, Rockville MD 20855.

§ 5.205 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6-57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991. Redesignated at 62 FR 13824, Mar. 24, 1997]

§ 5.210 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA-305)*. The Dockets Management Branch Public Room is located in rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301-443-1753.

(b) *Freedom of Information Staff (HFI-35)*. The Freedom of Information Public Room is located in rm. 12A-30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301-443-6310.

(c) *Press Relations Staff (HFI-40)*. The Press Offices are located in rm. 15-05, Parklawn Bldg., 5600 Fisher Lane, Rockville, MD 20857. Telephone: 301-443-3285; and in rm. 3807, FB-8, 200 C St. SW., Washington, DC 20204. Telephone 202-205-4144.

[62 FR 13824, Mar. 24, 1997]

§ 5.215 Field structure.

NORTHEAST REGION

Regional Field Office: 850 Third Ave., Brooklyn, NY 11232.

Northeast Regional Laboratory: 850 Third Ave., Brooklyn, NY 11232-1593.

New York District Office: 850 Third Ave., Brooklyn, NY 11232-1593.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Buffalo District Office: 599 Delaware Ave., Buffalo, NY 14202.

MID-ATLANTIC REGION

Regional Field Office: 900 U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: 900 U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201-2199.

Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202-1097.

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New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.

New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.

Florida District Office: 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901-3223.

MIDWEST REGION

Regional Field Office: 20 North Michigan Ave., rm. 510, Chicago, IL 60602.

Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.

Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207-3179.

Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401-1912.

SOUTHWEST REGION

Regional Field Office: 7920 Elmbrook Dr., Dallas, TX 75247-4982.

Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225-0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214.

St. Louis Branch: 12 Sunnen Dr., St. Louis, MO 63143.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180-N, Oakland, CA 94612-5217.

San Francisco District Office: 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Los Angeles District Office: 19900 MacArthur Blvd., suite 300, Irvine, CA 92715-2445.

Seattle District Office: 22201 23d Dr. SE., Bothell, WA 98021-4421.

[62 FR 13824, Mar. 24, 1997]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

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AUTHORITY: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–393); secs. 301, 351, 354–360F, 361 of the Public Health Service Act (42 U.S.C. 241, 262, 263b–263n, 264).

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]